

Office of Regulatory Affairs Strategies for Building an Integrated National Laboratory Network for Food and Feed

Report of the FDA Science Board
Food Emergency Response Network (FERN)
Cooperative Agreement Evaluation Subcommittee

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Abbreviations and Acronyms

AAFCO – Association of Animal Feed Control Officials
AFDO – Association of Food and Drug Officials
AFRPS – Animal Feed Regulatory Program Standards
AOAC – Association of Official Analytical Chemists
APHL – Association of Public Health Laboratories
CAP – Cooperative Agreement Funding Program
CoAg – Cooperative Agreement
CDC – Centers for Disease Control and Prevention
CFR – Code of Federal Regulations
CLG – *Chemistry Laboratory Guidebook*
DCLS – Division of Consolidated Laboratory Services (Virginia)
DHS – Department of Homeland Security
DOD – Department of Defense
DOE – Department of Energy
DOT – Department of Transportation
EPA – Environmental Protection Agency
FBI – Federal Bureau of Investigation
FERN – Food Emergency Response Network
FSIS – Food Safety and Inspection Service (USDA)
FSMA – Food Safety Modernization Act
IATA – International Air Transport Association
ICLN – Integrated Consortium of Laboratory Networks
IFSS – Integrated Food Safety System
ISO/IEC – International Organization for Standardization and the International Electrotechnical Commission
IT – Information Technology
LIMS – Laboratory Information Management System
LRN – Laboratory Response Network
LPRB-LRN – Laboratory Preparedness and Response Branch–Laboratory Response Network
MCAP – Microbiology Cooperative Agreement Program
MFRPS – Manufactured Food Regulatory Program Standards
MLG – *Microbiology Laboratory Guidebook*
NAHLN – National Animal Health Laboratory Network
NPO – National Program Office
ORA – Office of Regulatory Affairs (FDA)
PHEP – Public Health Emergency Preparedness (CDC)
PFP – Partnership for Food Protection
RFA – Request for Applications
USDA – U.S. Department of Agriculture
Vet-LIRN – Veterinary Laboratory Investigation and Response Network

Executive Summary

An interconnected network of accredited federal, state, local, tribal, and territorial laboratories is critical to ensuring the safety of the U.S. food supply and the development of the Integrated Food Safety System (IFSS). In 2004, as part of a national policy to defend the U.S. food supply against terrorist attacks, major disasters, and other emergencies, the Food Emergency Response Network (FERN) was created to integrate the nation's multilevel (i.e., federal, state, local, tribal, territorial) food-testing laboratories to detect, identify, respond to, and recover from a bioterrorism act affecting the safety of the food supply, or a public health emergency/outbreak involving the food supply. Since 2004, federal agencies have invested an estimated \$200 million in FERN. The majority of this investment has been in the FERN cooperative agreements with FDA and USDA-FSIS investing \$95.8 million and \$69 million, respectively. FDA has promoted the accreditation of state laboratories through cooperative agreement funding, investing more than \$50 million to fund these grants.

On November 11, 2014, the Office of Regulatory Affairs (ORA) requested that the FDA Science Board establish a subcommittee to evaluate current investments in: (1) the FERN cooperative agreement funding program (CAP), and (2) funding for state laboratories to achieve International Organization for Standardization (ISO) accreditation. The goal was to ascertain how ORA can advance and establish an effective integrated laboratory network among ORA, FDA Center, and state public health and food- and feed-testing laboratories. In response to this request, the Science Board created the ORA FERN Cooperative Agreement Evaluation Subcommittee on July 1, 2015. This report summarizes the results of the Subcommittee's review.

The Subcommittee found that FERN plays a critical role in establishing a national, integrated food safety system and has had a significant public health impact. FERN is instrumental in increasing national capability and capacity to detect, prevent, prepare for, respond to, and recover from threats to our country's food supply. FERN has successfully promoted integration of regulatory functions and emergency response preparedness in laboratories across the nation; however, with nearly 170 laboratories among the FDA, CDC, USDA-FSIS, and states, there are many more laboratories than FDA and USDA-FSIS have funds to support. Therefore, it is important for FDA (and consequently USDA-FSIS) to critically evaluate how FERN's limited funds can best be utilized to build a sustainable integrated laboratory network that meets public health and regulatory needs within an integrated national food safety system.

FDA's commitment to provide future funding opportunities to FERN will be required to sustain and ensure the realization of a fully integrated multilevel (e.g., federal, state, local) food-testing laboratory network. Such future funding increases should be to increase the depth and breadth of the program, meaning both further increases to the capacity of existing laboratories as well as expanding the numbers of laboratories receiving FERN support. Further, it is important that FDA modernize its food safety information architecture to ensure safe and secure transmission of data even while encouraging and facilitating efficient data sharing and collaboration across the entire network of food safety regulatory laboratories. Investments in FERN should save

money in terms of reduced public health costs as well as costs to industry, but metrics are needed to more directly assess public health impacts, functionality of the network as a system, as well as other goals, such as efficiency. Importantly, FDA has the opportunity, in collaboration with USDA-FSIS, to continue to develop and expand the FERN network. Specifically, the Subcommittee makes the following recommendations:

1. FERN consists of a group of diverse laboratories, and the focus on developing a basic level of capability/capacity across the network is a worthwhile goal that should be supported by the federal government. The baseline capabilities/capacities needed are not static and funding should be adapted to reflect these changing needs.
2. Efforts to build and sustain capabilities/capacities across FERN need consistent, multi-year funding. FDA should consider additional sources of funding, including cost-sharing or matching requirements for grant programs and recipients, where appropriate and/or possible.
3. While all laboratories should strive to improve capabilities, especially as some techniques become more routine, FDA should develop a plan for FERN that would consider the advantages of a tiered approach designed to avoid unnecessary duplication, for example, of expensive instrumentation across the network. Thus, while all laboratories should share a basic level of functionality, the advanced performance capabilities could be housed primarily or exclusively in regional/national facilities and/or centers to promote efficient use of existing expertise, equipment, and technical resources.
4. FERN funding agencies (i.e., FDA/ORA, USDA-FSIS) should continue to improve their engagement with the CDC/LPRB-LRN Program Office to discuss areas of common interest and combine efforts to improve testing capacity and capability within and across networks.
5. FDA should develop a technology-management plan to anticipate the eventual replacement of existing instrument platforms that employ newer and more advanced diagnostic methodologies. The plan should be developed in collaboration with the Centers of Excellence and include: platform selection, acquisition, upgrades/enhancements, along with corresponding technical training for personnel.
6. FDA should assume a holistic approach to addressing the IT and data-sharing needs of FERN partners. There is a strong public health need for an integrated information infrastructure that allows the seamless transmission of data in a secure environment that facilitates rapid analytics. Simply trying to fix the current system is unlikely to achieve this goal; a new system is needed. Such efforts must be guided by a comprehensive plan that is developed through stakeholder engagement (i.e., cooperative agreement laboratories) to meet the needs of an integrated food and feed safety system.
7. FERN leadership should develop clear objectives and adopt a set of metrics for both individual laboratories and the network, with appropriate targets and consensus as to what constitutes success and reflects the objectives.

8. FDA, in collaboration with other federal agencies, should convene an annual conference for the food safety laboratory network to engage scientists in professional education/development activities and facilitate the sharing of information.
9. FERN should have the capacity to support professional travel to conferences and/or for training and development.
10. FDA and its sister federal agencies (i.e., USDA-FSIS, CDC) should work with states on best practices for hiring and retaining scientists who are needed to perform this mission-critical work. Possible collaborators for initiating such efforts include the National Governor's Association and/or National Conference on State Legislatures. These organizations may be able to assist with the identification and/or development of models that can be considered for adoption by states nationally.
11. FDA should regularly communicate with all eligible laboratories to increase public health preparedness and participation in FERN training efforts.

The Subcommittee advises that the recommendations of this report be accepted with the utmost urgency and that our specific recommendations be considered as a means of ensuring the maintenance of a safe and secure food system. The FERN network represents one of the best national investments in improving the responsiveness of our combined federal, state, local and territorial governments; the development of IFSS; and the prevention of foodborne disease.

1. Introduction

Foodborne diseases are a significant public health issue in the United States, causing an estimated 48 million illnesses, 125,000 hospitalizations, and 3,000 deaths annually, according to the Centers for Disease Control (CDC).^{1,2,3} The U.S. food system is complex, and managing risks throughout the supply chain is a challenging task that requires an integrated, risk-based approach. Recognizing this, Congress enacted the *Food Safety Modernization Act* (FSMA) in January 2011, providing the first major overhaul of food safety oversight at the U.S. Food and Drug Administration (FDA), which oversees the safety of approximately 80% of the food supply, in nearly 70 years.⁴

FSMA directs FDA to build, in partnership with other federal, state, local, tribal, and territorial food safety agencies, an Integrated Food Safety System (IFSS) that is focused on prevention and enhanced collaboration across these safety agencies.⁵ Specifically, FSMA directs FDA to develop and implement strategies to leverage and enhance food safety and defense capacities of state and local agencies, including establishing a program for the testing of food by accredited laboratories⁶ and the Integrated Consortium of Laboratory Networks (ICLN).⁷

An interconnected network of high-quality federal, state, local, tribal, and territorial laboratories is critical to ensuring the safety of the food supply and the development of IFSS. In 2004, as part of a national policy to defend the food supply against terrorist attacks, major disasters, and other emergencies, *Homeland Security Presidential Directive 9* (HSPD-9) required the development of nationwide laboratory networks for food, veterinary, plant health, and water quality (e.g., FERN, Vet-LIRN, NAHLN, EPA) that: (1) integrate existing federal- and state-government laboratory resources, (2) are interconnected, and (3) utilize standardized diagnostic protocols and procedures.⁸

In response to HSPD-9, the Food Emergency Response Network (FERN) was created to integrate the nation's multilevel (i.e., federal, state, local, tribal, territorial) food-testing laboratories to detect, identify, respond to, and recover from a bioterrorism act or public health emergency/outbreak involving the food supply. FERN has four main objectives:

- 1) Prevent attacks on the nation's food supply by providing means for early detection of threat agents;
- 2) Prepare member laboratories (i.e., federal, state, local, tribal, territorial) to respond to food-related emergencies;

¹ <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>

² Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. 2011 (Jan.). Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases*, 17(1):7–15.

³ Scallan E, Griffin PM, Angulo FJ, Tauxe RV, Hoekstra RM. Foodborne Illness Acquired in the United States—Unspecified Agents. *Emerging Infectious Diseases*, 17(1):16–22.

⁴ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

⁵ FSMA Act – Section 209

⁶ FSMA Act – Section 202

⁷ FSMA Act – Section 203

⁸ *Homeland Security Presidential Directive/HSPD-9*. 2004 (Jan. 30), <http://fas.org/irp/offdocs/nspd/hspd-9.html>

- 3) Provide and coordinate regional and national surge capacity for laboratories;
- 4) Assist in recovery efforts to restore confidence in the food supply following a threat or actual emergency.

FERN, which is coordinated by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), provides multiple areas of support to member laboratories, including cooperative agreement funding. Currently, there are 170 member laboratories in FERN, and through cooperative agreements, FDA funds 33 state laboratories; the latter include 13 chemistry laboratories, 15 microbiology laboratories, and 5 radiology laboratories. These laboratories are intended to provide increased capability and capacity for conducting sample analyses of food products for the rapid detection and identification of large-scale food contaminations, intentional or accidental, and have provided these functions for the FDA in most of the large-scale national food events since their initial funding. According to FDA, approximately \$95.8 million has been awarded to state, local, tribal, and territorial laboratories since 2005, and an estimated \$500,000 is spent internally each year to support FERN activities.

On November 11, 2014, the Office of Regulatory Affairs (ORA) requested that the FDA Science Board establish a new subcommittee to evaluate the current investments in: (1) the FERN cooperative agreement program, and (2) funding for state laboratories to achieve International Organization for Standardization (ISO) accreditation.⁹ The goal was to ascertain how ORA can advance and establish an effective integrated laboratory network among ORA, FDA Centers, and state public-health and food- and feed-testing laboratories. In response to this request, the ORA FERN Cooperative Agreement Evaluation Subcommittee of the Science Board to the Food and Drug Administration (Subcommittee) was established on July 1, 2015 (Appendix A).

2. Charge to the FERN Cooperative Agreement Evaluation Subcommittee

The scope of work for this Subcommittee includes evaluation of three existing FDA state cooperative agreement program (CAP) grants to enhance FERN laboratory capability/capacity, help laboratories attain accreditation, and integrate the food safety community, and to assess how these agreements or other approaches can best be utilized to build an integrated laboratory network among public health and food- and feed-testing laboratories.

Specifically, the question to the Subcommittee is how can the Agency continue to build a sustainable, integrated, and mutually reliant laboratory network that meets the public health and regulatory needs under an integrated national food safety system? *Integrated* refers to the combining of both regulatory and emergency response functions within each laboratory, and *mutually reliant* refers to the capacity and capability of laboratories — be they state, CDC, FDA,

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<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm423187.htm>

USDA-FSIS, or food- and feed-testing laboratories — to be able to rely on each other to provide testing and regulatory data and analyses that are reliable in their respective functions.

The Subcommittee's scope of work also includes an assessment of the technical areas of data quality and sharing, proficiency testing, method harmonization, and analytical results reporting sufficient to allow recommendations that could facilitate the rapid and efficient interchange of laboratory results in an integrated laboratory network.

Questions from ORA for the Board's FERN Subcommittee to Address:

- 1) How can we further promote and build an integrated laboratory network among the food regulatory laboratories of ORA, FDA Centers, USDA's FSIS, and state health departments as part of developing a stronger system of mutual reliance in the food and feed program?
- 2) What are the appropriate scientific, analytical and technical capabilities required to facilitate the sharing of laboratory data between public health and regulatory agencies in a timely and efficient manner to enhance consumer protection?
- 3) What are the realized benefits and limitations to these FERN Network, laboratory accreditation, and Laboratory Associations (e.g., APHL, AFDO, AAFCO) cooperative agreements, and how can we improve upon the current utilization of the results of these agreements?
- 4) How impactful to public health has this building of an integrated laboratory network and promotion of our state laboratories been to date? Explore case studies.
- 5) What would be appropriate metrics to measure the effectiveness of these integration strategies in promoting a national integrated laboratory system?

3. Evaluation Process

The evaluation process used by the FERN Subcommittee consisted of a review of background materials; meetings and discussions with FDA, staff from state and local laboratories, and others; and a site visit. The Subcommittee met regularly via conference call to review documents and conduct interviews.

The Subcommittee was provided with background documentation on FERN by the FDA-ORA Office of Partnership and the FERN National Program Office. The Subcommittee was provided with the latest available progress reports covering the performance dates from September 1, 2015, through February 29, 2016, from 24 randomly selected laboratories provided by the FDA. Ten reports represented FERN/CAP-funded laboratories; another ten reports represented the ISO/IEC laboratories; while five reports represented ISO/IEC self-assessment gap-analysis. Budget plans from five state public health or agriculture laboratories that were awarded funds for both chemical and microbiology preparedness areas were evaluated for consistency of expenditures relative to expected outcomes. Additionally, the Subcommittee reviewed an interim progress report, dated March 30, 2016, from the Association of Public Health Laboratories (APHL) for a cooperative agreement for "Building an Integrated Laboratory System

to Advance the Safety of Food and Animal Feed.” Finally, the Subcommittee reviewed detailed budget information from FY15.

The Subcommittee also invited FERN-relevant presentations by FDA and other organizations and conducted several interviews with management and leadership staff at laboratories in five non-funded states, including Florida, Indiana, New York, Pennsylvania, and Utah during separate teleconferences in February and March 2016. Presenters and interviewees, along with their institutional affiliations, are listed in Appendix B; questions drafted by the Committee are provided in Appendix C.

To further inform its review with real-world data and information, the Subcommittee conducted a site visit in Richmond, Virginia, at the Division of Consolidated Laboratory Services (DCLS) on January 12, 2016. This FDA CAP laboratory was chosen for a site visit in part because it is generally regarded as a well-functioning, full-service laboratory, exemplary by virtue of its efficient, integrated, collaborative, and productive operations that are highly valued by FERN. The Richmond laboratory serves as a prime example of how federal resources could be, for example, leveraged in order to inform and train personnel from other facilities, tapped as a source of best practices, and modeled by other laboratories. Also, the Richmond laboratory is funded through cooperative agreements by both FDA and USDA-FSIS for chemical and microbiological analyses. In addition, USDA-FSIS, through its CAP, supports DCLS as a training center for other FERN laboratories.

To produce the present report, the Subcommittee chair assigned individual Subcommittee members to compose first drafts of various chapters (i.e., Funding, Metrics, Data Analytics, Training and Development, and Impact on Public Health). The chair consolidated the drafts and compiled the final report with the assistance of a technical writer-editor.

4. Overview of FERN

FERN’s mission is to integrate the nation’s food testing laboratories at the federal, state, and local and tribal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. FERN’s objectives are to provide for an early means of detecting threat agents in the U.S. food supply; prepare the nation’s laboratories to be capable of responding to food-related emergency events; provide surge capacity that will allow the nation to respond to food emergency events; and enhance the ability of the country to restore confidence in the food supply after an emergency or in response to a threat. FERN achieves its objectives by conducting laboratory testing and targeted surveillance programs; developing standardized food testing methodologies; providing chemical, microbiological, and radiological training activities; conducting proficiency testing; and facilitating communication among member laboratories.

Federal, state, local, tribal, and territorial government food-testing laboratories that have chemical, biological, and/or radiological analytical capabilities can apply to become a member of FERN. As stated previously, there are currently 170 member laboratories in FERN, including

public health, agriculture, environmental, and veterinary diagnostic laboratories. Individual laboratories are categorized based on laboratory capability responses posted on the FERN website Laboratory Directory (LabDIR). Each laboratory has separate tabulations for each discipline registered, as well as one overall number obtained by totaling all of the disciplines registered for in LabDIR, and this is combined with the responses to the general laboratory questions for an overall result. Each laboratory’s total discipline-specific and overall scores determine the laboratory’s category. This tiering process facilitates the laboratory selection process for a FERN activation event. The categorization serves as a tool for FERN to view the capabilities of its member laboratories in real time and can be used as any other tool in the National Program Office/Regional Coordination Center tool belt, but is not an official requirement in the process of “activation” of FERN in responding to an emergency event. The individual assessment of laboratory capability/capacity in the FERN regions is done by the regional coordinators, in coordination with the National Program Office, in response to specific emergency events as part of the official “activation” of FERN. Several federal agencies are FERN partners, including FDA, USDA-FSIS, CDC, DOD, FBI, EPA, DHS, and DOE.¹⁰ The organizational structure of FERN is shown in Figure 1.

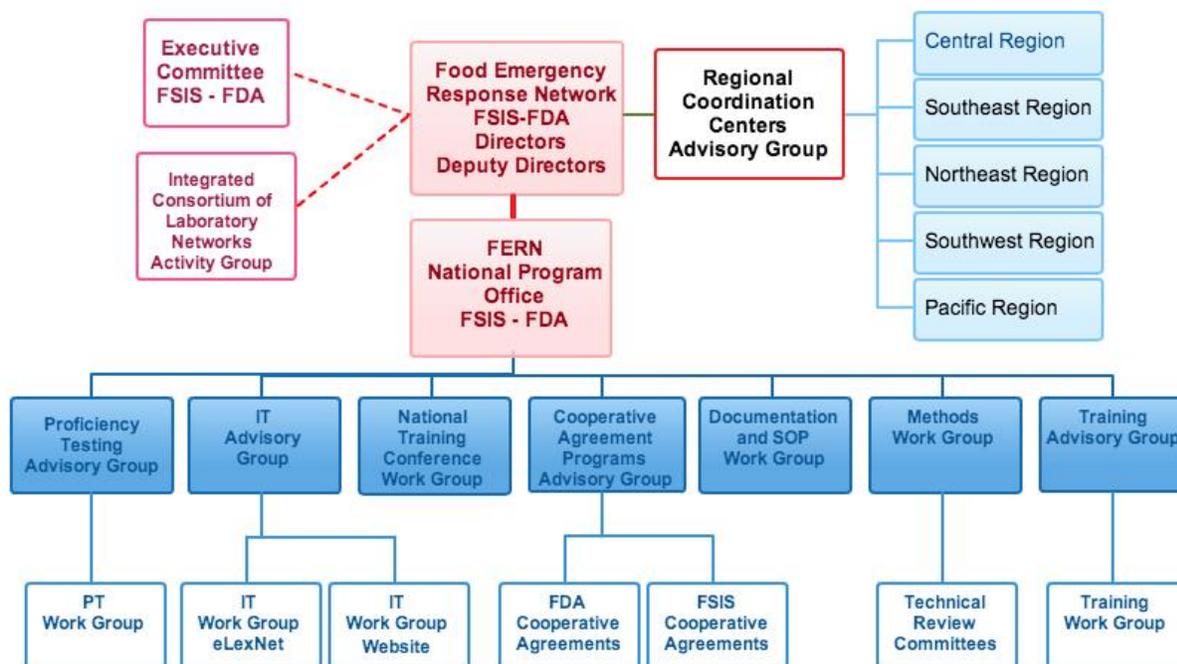


Figure 1. FERN Organizational Structure. From: *Biennial Report to Congress on the Food Emergency Response Network*. 2013 (Nov.). Food and Drug Administration.

Funds have been invested in FERN by both FDA and USDA-FSIS to enhance laboratory capacity/capability and by FDA to assist state laboratories in attaining laboratory accreditation

¹⁰ Frequently used abbreviations and acronyms are defined in the Abbreviations and Acronyms section at the beginning of this report.

in accordance with ISO International Electrotechnical Commission (i.e., ISO/IEC 17025:2005). ISO is an independent, non-governmental organization made up of members from the national standards bodies of 162 countries (<http://www.iso.org>). Accreditation by ISO is seen by many as a gold standard for establishing national laboratory standards and implementing a fully integrated national food safety system with mutually acceptable analytical data. Forty-six state FERN laboratories are currently being funded by the ISO/IEC 17025:2005 Cooperative Agreement. In 2015, findings of the food samples by these FDA/FERN-ISO-supported laboratories triggered two nationwide recalls of ice cream products for *L. monocytogenes* contamination.

In addition, in 2014–2015, 15 FERN Microbiology Cooperative Agreement Program (MCAP) laboratories, many also funded to obtain laboratory accreditation through the ISO CAP, participated in FDA’s large-volume surveillance assignment, analyzing imported and domestic avocados for the presence of *Salmonella* and *L. monocytogenes*. Their sample results were used to establish statistically relevant risk assessments as well as to support FDA regulatory decisions.

Selected state laboratories that are also members of FERN are the primary servicing laboratory for their respective state’s regulatory agency that is enrolled in the FDA’s Manufactured Food Regulatory Program Standards (MFRPS) and/or Animal Feed Regulatory Program Standards (AFRPS). These two sets of standards are used by the states to guide continuous improvement in food manufacturing and animal feed programs. Standard #10 of the MFRPS and AFRPS addresses state laboratory services and their quality management systems. Many of the states with FERN-supported laboratories that seek to attain laboratory accreditation participate in the FDA’s Rapid Response Teams, a program created to address the need for improved, integrated, and rapid responses to food- and feed-related emergencies.

A cooperative agreement with the Association of Public Health Laboratories (APHL), the Association of Food and Drug Officials (AFDO), and the Association of Animal Feed Control Officials (AAFCO) has also been established to further regulatory laboratory integration. This agreement seeks to facilitate long-term improvements in the national food and animal-feed safety system by strengthening multi-disciplinary laboratory collaboration and equivalency, thereby advancing laboratory accreditation, and building an integrated community of federal, state, local, and tribal regulatory laboratories.

5. General Findings

This section summarizes the results of the Subcommittee’s review of: (1) the FERN CAP, and (2) funding for state laboratories to achieve ISO accreditation. The review includes an assessment of Public Health Impact (Section 5.1 below), Funding Mechanisms (Section 5.2), and Metrics (Section 5.3). The report also addresses two areas where the Subcommittee felt that improvements would increase the effectiveness of FERN: Data Analytics (Section 5.4) and Training and Workforce Development (Section 5.5).

5.1 Public Health Impact

FERN plays a critical role in establishing a national integrated food safety system by increasing national capability and capacity to detect, prevent, prepare for, respond to, and recover from threats to the country's food supply. Because the FERN CAP laboratories bring training assets as well as provide equipment and personnel, they are able to rapidly respond to these threats to the food supply. They also provide FDA with increased capacity and capability in fulfilling its responsibility to respond to such threats. The following sampling of a range of significant national and international incidents highlight the critical value of the FERN laboratories in helping maintain a safe food and feed supply.

FERN CAP laboratories were instrumentally important, for example, in the national response to the melamine adulteration incidents of 2007 and 2008 that affected the safety of the food and feed supply in China and elsewhere. In the pet-food adulteration incident of 2007, FERN chemistry laboratories worked with FDA laboratories to develop and validate a screening method to detect this toxic industrial compound in pet food. The FERN laboratories analyzed more than 200 samples as part of an FDA assignment to determine the extent of contamination of the nation's pet-food supply. The subsequent melamine adulteration incident involving milk and infant formula products (2008–2009) spurred FERN laboratories to develop two new methodologies to detect melamine and melamine by-products in milk-containing foods. The FERN laboratories then analyzed more than 300 samples, providing additional analytical surge capacity to FDA field laboratories in protecting public health.

In addition, following the 2010 Deepwater Horizon oil spill in the Gulf of Mexico, FERN CAP laboratories provided much-needed method development and analytical capacity that allowed a safe reopening of the Gulf waters to commercial fishing. FERN laboratories, along with an FDA laboratory, developed and validated a new rapid-screening method to detect petroleum contamination in seafood, decreasing by half the amount of time that previous analytical methods had required. The FERN laboratories were thus able to rapidly analyze more than 460 samples, making possible more rapid access to the Gulf by the commercial fishing industry.

In 2011, FERN radiological CAP laboratories were activated to respond to the Fukushima, Japan nuclear disaster. FERN laboratories, in collaboration with the FDA radiological specialty laboratory, participated in method development and validation; both federal and state sample testing laboratories used these FERN methods and its equipment for rapid and extensive testing of suspect products. These FERN accomplishments helped ease the public's fear of possible radiological contamination.

Finally, the FDA engaged FERN CAP laboratories to expand the testing capacity to detect arsenic in juices and rice products in 2012. FERN chemistry laboratories were activated to analyze backlogged samples, allowing a quicker determination of the extent of arsenic contamination in these products.

An example of the integration of both the FERN cooperative agreement program and the ISO accreditation program would be the 2015 nationwide recalls of ice cream products due to *L.*

monocytogenes contamination. These recalls were triggered by the analytical work of FDA/FERN-ISO-supported laboratories, with the rapid analytical data acceptance facilitated by the laboratory quality systems being installed with the ISO cooperative agreement funding.

5.2 Funding Mechanisms

The Subcommittee evaluated three existing funding agreements, which were funded in FY15 as follows: (1) FDA FERN Cooperative Agreement Continuation Program, U18 (\$10.1M); (2) ISO/IEC 17025:2005 Accreditation for State Food Testing Laboratories, U18 (\$9.3M); and (3) Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed, U18, (\$1.1M).¹¹ The FERN funding mechanism has existed since FY05, and the other two funding agreements have been in place since FY12,¹² with year-to-year funding levels remaining relatively consistent over the last eight years (Figure 2).¹³

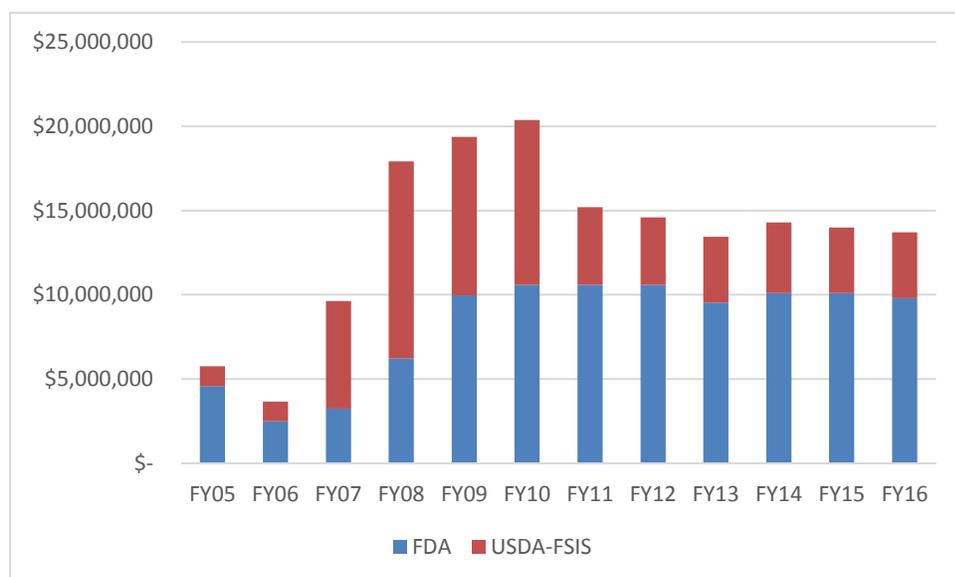


Figure 2. FERN Funding Levels 2005–2016

The FERN Cooperative Agreement Program offers funding on a competitive basis to state, local, tribal, and territorial FERN laboratories to increase analytical capacity and expertise during events that require surge capacity testing of samples, including the provision of supplies, personnel, facility/equipment upgrades, training in current testing methodologies, participation in proficiency testing, participation in method enhancement activities and analysis of surveillance and emergency outbreak samples.¹⁴ In FY15, the FERN CAP provided a total of \$10.1M to 26 awardees¹⁵, including 14 chemistry laboratories, 14 microbiology laboratories,

¹¹ Indicative of the funding range, in prior years, this third CAP funding stream had been as high as \$1.5M.

¹² In FY15, the three FERN funding streams were consolidated into one.

¹³ In FY13, federal budget sequestration impacted these three programs, wherein #3 incurred a 50% cut, for example. While most programs' funding was eventually restored, some FERN programs have not been restored to pre-sequestration levels.

¹⁴ <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-15-019.html>

¹⁵ Some laboratories have more than one discipline.

and 5 radiology laboratories; the period of performance for each award was one year with the possibility of up to four additional years of funding, depending on performance and continued availability of federal funds. FDA funding for the FERN CAP has been relatively level (FY12 = \$10.6M; FY13 = \$9.5M; and FY14 = \$10.1M) but has been limited to current FERN laboratories. The selection process for the cooperative agreements considered several criteria, including: (1) current capabilities and capacities of the laboratories; (2) abilities of laboratories to perform large-scale testing for FERN, if requested to do so; and (3) geographical distribution of selected laboratories across the nation.¹⁶

The ISO/IEC 17025:2005 Accreditation for State Food Testing Laboratories Cooperative Agreement Program has a \$9.3M annual appropriations limit and provides funds to 46 state food testing laboratories to obtain, maintain, and/or expand laboratory accreditation to recognized international standards (ISO/IEC 17025:2005). The goal of this ISO-related funding is to achieve a nationally integrated food safety system that can be further expanded. The agreement's purpose is three-fold: (1) conduct food analyses in accordance with the procedures of an ISO/IEC 17025:2005-accredited laboratory, (2) maintain the accreditation of presently accredited laboratories and/or expand the scope of ISO to additional sections within the laboratory, and (3) achieve laboratory conformance with Standard #10 of the Manufactured Food Regulatory Program Standards (MFRPS). Standard #10 requires that all food testing performed for the program be done in regulatory laboratories that are accredited in accordance with ISO/IEC 17025:2005, or are implementing quality systems on par with ISO/IEC 17025:2005. The intended outcome is for microbiological and chemical food analyses performed on behalf of state manufactured food regulatory programs to be conducted in compliance with the procedures in an ISO/IEC 17025:2005-accredited laboratory.

The Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed Cooperative Agreement Program was established to strengthen multi-disciplinary laboratory collaboration and equivalency; establish a platform for building an integrated laboratory community; and advancing the sharing, equivalency and acceptability of laboratory results.¹⁷ This CAP, which is limited to national non-profit organizations, guarantees support for one year, with the possibility of up to four additional years of funding, depending on performance and continued availability of federal funds. The CAP has an annual budget of \$1.5M with a period of performance from September 2012 through August 2017; and, as of this writing (September 2016), this is the fifth year in which APHL has received this award. APHL is required to sub-award a minimum of 25% of the funds received to at least two different associations, one representing state manufactured food regulatory officials (e.g., Association of Food and Drug Officials [AFDO]) and the other association must represent state animal feed regulatory officials (e.g., Association of Animal Feed Control Officials [AAFCO]).

The Subcommittee reviewed the latest available progress reports covering the performance dates from September 1, 2015, through February 29, 2016, from 24 randomly selected

¹⁶ The FY15 FERN RFA restricted eligibility to only those laboratories that were receiving funding at the time of application.

¹⁷ <http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-12-025.html>

laboratories provided by the FDA/ORA FERN Program Office. Ten reports represented FERN-CAP-funded laboratories; another ten reports represented the ISO/IEC laboratories; while five reports represented ISO/IEC self-assessment gap-analysis. Budget plans from five state-level public health or agriculture laboratories that were awarded funds for both chemical and microbiology preparedness areas were evaluated for consistency of expenditures relative to expected outcomes. An effort was also made to determine each of the laboratories' pre-funding status prior to September 1, 2015, to evaluate the effectiveness of the program's ability to achieve the targeted outcomes. Finally, the Subcommittee reviewed APHL's March 30, 2016, interim CAP progress report for Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed.

From the review of the progress reports, we made a number of findings.¹⁸ Generally, FERN's existence expands the FDA's laboratory-based regulatory capacity as the network simultaneously serves in the promotion of emergency-related food safety through the sharing of regulatory data. FERN acts as an additional resource, enhancing FDA's existing capacity.

Meaningful progress has been made in performance areas such as sample analysis or surveillance events; method extension or enhancement studies and proficiency testing (PT) challenges. All the grantees were involved in increased sample analysis or threat-related surveillance testing; the number of events ranged from one to nine, with an average of four events per laboratory. Of special note, expenditures for acquiring necessary scientific expertise comprised the largest budget line item, with the combined chemistry and microbiology personnel expenses (approximately \$144,000/FTE), totalling 50% of the grant, and ranging from 22 to 86% of the total annual award per grantee. On average, grantees reported six FDA-purchased and/or loaned equipment/instrumentation acquisitions, directly enhancing the network's overall testing capability and capacity. Nine of the reviewed grantees completed 19 method extension/enhancement studies. Furthermore, all laboratories completed two PT challenges between September 1, 2015, through February 29, 2016, and some completed as many as four. Historically, since 2004, the FERN PT program has administered 63 separate PT exercises involving microbiology, chemistry, and radiochemistry.

An FY15 budget review from a cross-section of five (~20%) of the 26 participating state laboratories revealed funds were used in an efficient manner, supporting expenditures and activities that contribute to expected outcomes. Pre-assessment gap analyses indicate that laboratories that were selected to receive funds for ISO/IEC 17025:2005 had well-designed and high-quality management infrastructure with an enhanced likelihood to achieve ISO/IEC 17025 accreditation. Reports reviewed by the Subcommittee from 19 laboratories revealed that six were ISO/IEC 17025:2005 accredited, four had completed and submitted their 17025 application, and the remaining nine were on schedule with their respective accreditation action plan. At present, 18 of 36 awardees (50%) are ISO/IEC 17025:2005 accredited.

¹⁸ Unfortunately, APHL's year-four report was not organized in a standardized manner that would allow the Subcommittee to report progress across the nine activity areas as defined in the Funding Opportunity Announcement.

5.3 Metrics

Since its inception, FERN has established and maintained cooperative agreements with state, local, and tribal public health or agriculture laboratories. The cooperative agreements require that each funded/grantee laboratory meet criteria regarding staff training, analysts' proficiencies, method development, testing-sample processing time (i.e., from the time that a sample is received to the time that testing results are reported), and dissemination of test results, where possible, across the national network. Continuation of funding, which is renewable annually for up to five years, is contingent upon the laboratory fulfilling the expectations set forth in the cooperative agreement.

At the FERN national program level, FDA and USDA-FSIS jointly determine the aggregate need for capability and capacity to respond to food-related emergencies. Capability (the ability to accurately perform the laboratory testing set forth in the cooperative agreement) and capacity (the ability to conduct the number of tests agreed to in the cooperative agreement and in the time specified) are periodically assessed through exercises. FDA and USDA-FSIS have developed metrics at the agency level and the national-program level (Appendix D), not all of which have been included in the cooperative agreements or tracked at an enterprise level.

The Laboratory Response Network (LRN), managed by the CDC, has an analogous mission to that of the FERN and responds to public health emergencies, especially those involving selected agents. The Subcommittee agreed that many of the metrics used currently by the LRN could readily be adapted for use by the FERN. The LRN capability assessment is focused on five functions:

- 1) Managing laboratory activities,
- 2) Performing sample management,
- 3) Conducting testing and analysis for routine and surge capacity,
- 4) Supporting public health investigations, and
- 5) Reporting results.

Each function consists of specific tasks, which are assessed by one or more distinct performance measures. The Association of Public Health Laboratories (APHL) has also developed an extensive set of metrics for cooperative agreements (Appendix D), some of which could be adapted by the FDA and FERN.

5.4 Data Analytics

Access to high-quality data collected throughout the food system, as well as the ability to conduct meaningful statistical analyses on such data, is critically important to implementing an integrated food safety system. Data analytic tools and infrastructure — including computational capacity, data storage, and communications capabilities that allow efficient data acquisition, retrieval, and sharing among laboratories — as well as up-to-date statistical software and staff competencies, all contribute to timely and efficient utilization of data for risk-based decision-

making. Given the objectives of FERN, it is essential that the network's data analytics¹⁹ functions are working well and seamlessly across all partnering institutions.

The FERN Subcommittee reviewed multiple reports, conducted site visits, and interviewed a number of collaborative laboratories. Findings include the fact that, today, FERN laboratories generate data and attempt to transfer data to FDA by email and fax, after which it is generally re-entered manually into statistical software such as spreadsheets and analysis software. The Subcommittee believes that the archaic transfer mechanisms and the manual re-entry of data poses a major risk to data integrity, and is a stumbling block to willingness/ability to share. Among the many issues that apparently drive this situation is an IT firewall/cybersecurity concern that is designed to reduce risk of access to FDA data systems and thereby isolate them from their partners in the FERN network. Because the FDA must use data to serve its regulatory mission, functions, and actions, the security and integrity of that data is paramount. Nevertheless, if the basic security concerns preclude a desire and willingness of fully vetted partners to contribute, it in essence has the ability to cripple the intent of the network.

FDA's security/integrity concerns, relative to its FERN partners, compromise the adequacy of data sharing and thus the capacity of the entire system to function efficiently and effectively. Attempts have been made to develop alternate approaches such as using an FDA-owned computer located at the partnering association for the data transfer. However, these attempts have also failed to find a functional process. This matter deserves a high-level policy discussion and consideration as to how the FDA's IT system can be changed to also advance the success of an integrated national foodborne illness prevention and mitigation program. In the end, the only solution may be to develop a new modern IT infrastructure, built from the ground up with both adequate security as well as ease of access and use in mind.

Currently, regulatory inspection data also are manually entered into FDA computers from the FERN network. Double entry results in significant errors and lost time. Implementation of a very basic file transfer capability, as an interim measure, should be explored to address these manual entry data risks. The Subcommittee recognizes that a balance must be achieved that serves data security needs and also preserves some degree of access that is dramatically improved from the status quo and thus serves the public health needs for mitigating food-related illness. Decision making by FDA must be evidence based, and the FERN network should be recognized as an important part of the foundational knowledge base.

The Subcommittee came to realize through its interviews and observations that the independence of state laboratories may exacerbate the data-sharing problem; however, this should be mitigated once a modern IT-infrastructure — delivering security and accessibility — is incorporated into the FDA system. When FERN is establishing various events for collaboration, there is a clearly perceived value and appreciation on both the state and FDA laboratory side. That goodwill is visibly eroded by relegating key data unusable when placing it behind partner-

¹⁹ For the purposes of this report, the Subcommittee defines *data analytics* as the combined capabilities that facilitate accessing and sharing relevant data within FERN and completing appropriate computations on the data in a quick and efficient manner.

inaccessible firewalls.

The eLEXNET presents a theoretical design possibility by allowing a dual construction (i.e., having both a firewall-protected FERN functionality and a non-firewall-protected food data analytics sharing component), and this approach might make sense for FDA. However, the lack of functionality on the non-firewall side defeats the purpose and may again discourage the use of eLEXNET. In addition, because eLEXNET is a fairly old IT system, the question arises as to whether it is more efficient to support the current system or redesign with a modern IT infrastructure that equally addresses security and access. This may sound simplistic, but weighing the lessons learned and the newer approaches in database design may point to greater value in the long-term gains to be realized from redesigning and building anew.

The Subcommittee also considered the IT needs of FSMA and determined that there is a concern that FSMA needs may be decreasing much-needed attention to FERN. This is yet another impediment to addressing the complicated FERN resource issues. Regardless of the competing interests between different FDA functions, managing legacy data is not trivial and must be taken into account when the IT system is redesigned to achieve serious gains in functionality. In conclusion, the task of migrating legacy data must be incorporated from the outset in the planning of any future effort.

Thus, moving data into the FDA/USDA-FSIS system is a technical problem that imposes a burden on staff time and compromises database quality control. At the center of this challenge is eLEXNET, an outdated data management system that is currently undergoing updating and improvements and that is not protected by a cyber-secure firewall. Many laboratory staff, consequently, do not see a benefit in using this system, largely because, unlike staff of the state department of health or other relevant state agency, they do not generally need to access this data that is collected from across the states. Some IT effort, such as the Partnership for Food Protection (PFP) Information Technology (IT) workgroup, is now being devoted to ameliorate this barrier to a more seamless transmission of data from the state level into the fire-wall-protected FDA/USDA-FSIS system. It seems clear that any solutions to this data migration matter will be more successful if their design is driven by the information needs of the users.

5.5 Training and Workforce Development

Optimal response to food emergencies requires that several disparate types of technical, material, and human resources be in place at all times, and it requires that effective protocols be established, understood, and carefully followed. For example, laboratories require: (1) trained and expert staff who have appropriate levels of relevant educational background; (2) staff access to continuous training and educational opportunities in order to maintain and increase skills and knowledge; (3) up-to-date equipment and facilities to be able to assist with analyses and seamlessly and efficiently share data and information within the network, (4) adequate communication capacity in order to engage other networked laboratories and to share data and information, as needed; and (5) funding to respond to emergencies as they arise.

FERN has a strong focus on training and workforce development among the network of laboratories that it supports and with which it collaborates. Specifically, training is offered in a number of areas that have relevance to responding to bioterrorism and infectious disease outbreaks: detection of radiological, chemical, and microbial agents; detection of select-agents (e.g., toxins/poisons, disease-causing viruses and bacteria); and rapid-detection methodologies.

The FERN network also has helped develop and promote the use of more up-to-date technologies for laboratory analyses. This, in turn, results in increasing the capacity of the workforce in FERN-affiliated laboratories. The network engages its members in laboratory proficiency testing exercises — as well as quality assurance and auditing training — that help improve practices across a range of functions and responsibilities of the FERN system.

These activities have supported not only training and development of the existing laboratory workforce but also the ability to recruit new scientists who are more attracted to working in a laboratory environment that is more state-of-the-art and operational. Moreover, because the FERN network makes available electronic communication and collaboration tools, these assets have the potential to assist personnel across collaborating laboratories in learning how to utilize and adopt new practices that increase efficiency and accuracy of laboratory functions.

The Subcommittee believes the value of the FERN network for enhancing training is apparent. The Richmond, Va., laboratory is funded by the USDA-FSIS to serve as a training center for other laboratories. The Subcommittee visited the Richmond laboratory, which has developed a well-equipped training facility. The Subcommittee learned of several anecdotal examples of state laboratory scientists who had participated in FERN network training then becoming the *de facto* subject-matter experts on those issues within their own states.

The Subcommittee believes that the FERN-enabled training is a valuable way for the federal government to leverage the personnel in the FERN network to share best practices and to train personnel across the FERN system. However, while some training efforts are broadly available, other training efforts only benefit laboratories that are part of the FERN network. Another issue that needs to be addressed is travel for training. State laboratory representatives with whom the Subcommittee spoke indicated that most of their staff travel is funded by grants and that even when there are grants, there are several levels of approval that can create obstacles to staff access to training. States need both access and funding to participate in training or more training solutions such as the Richmond laboratory's creative "training in-the-box" system that does not require travel.

In terms of workforce development, there are several ways that the FERN network is effective, and could be more effective. The very process of engaging the FERN network laboratories in development and deployment of new laboratory technologies, as well as in efforts to boost staff proficiency in applying laboratory methods and adopting new electronic systems, indirectly helps to support the professional development of the laboratories' workforce. However, the program seems to have reduced the frequency of conferences and other venues that help to build professional networks that in turn promote continuing development of the

scientists in the FERN laboratories. Also the ability to attend professional conferences helps enable the recruitment and retention of the best scientists.

In addition, the Subcommittee learned of a number of obstacles caused by states' personnel processes that were adversely impacting the network's national capacity to be effective. Some of these problems include: the inability to offer competitive salaries, excessive staff turnover, and lack of career mobility for scientists within some state personnel systems. These problems are not easy to address, but they are solvable.

Specifics concerning FERN's workforce-related challenges include the fact that salaries are not sufficiently competitive. Evidence of this relates to staff retention. For example, state laboratory staff have turned over four times in 12 years. To address this handicap, states would need to update personnel classifications. To the extent that FDA's recent efforts to evaluate salary grades of ORA field staff might have an impact on FERN laboratory staff salaries is not known.

Another workforce issue concerns professional development, for which there is a large need. This includes the need to increase opportunities for internships and fellowships. Perhaps FERN grants could be used to support attendance at conferences, enhance professional development, and create a learning environment that is attractive to scientists and characteristic of exchange of scientific discoveries and information (e.g., annual meetings of scientific societies). The current lack of funding for such has eliminated this important opportunity for competency development and education. Travel funds that promote professional development and networking are a part of this need and would contribute immensely to advancing this valuable component of developing and expanding our scientists' professional networks. Training in the FERN laboratories, on the other hand, is an impressive counter to the limitations in professional development opportunities. For example, the training-in-the-box approach allowed for regional lab staff to join remotely in training exercises where materials and reagents were shipped to remote locations and virtual training programs using voice and video connection allowed for remote hands on training. The Subcommittee was impressed with this creative approach to training.

6. Conclusions

The goal of this report is to ascertain how ORA can advance and establish an effective nationally integrated laboratory network among ORA, FDA Center laboratories, and state public health and food- and feed-testing laboratories. Specifically, the Subcommittee was asked to address five questions; below are the responses to these questions based on the Subcommittee's review.

6.1 Promoting and Building an Integrated Laboratory Network

Question 1: How can we further promote and build an integrated laboratory network among the food regulatory laboratories of ORA, FDA Centers, USDA's FSIS, and state health departments as part of developing a stronger system of mutual reliance in the food and feed program?

An evaluation of the current system including FERN indicates that efforts to date have laid the groundwork for a stronger, more integrated network of food regulatory laboratories that have a much greater scientific capacity and function in a more rapid and coordinated fashion in response to national food safety emergencies. At the same time, the Subcommittee concludes that there is a need to double down on the effort to strengthen the nation’s food regulatory laboratory system. The existing network could be made to operate much more effectively and efficiently if it were possible to overhaul systems for reporting and accessing data. As noted below, modern computer security systems should be able to embrace secure means of data transfer that allow for free exchange of data and analyses yet do not compromise computer systems within federal, state, and local governments. Second, the existing network could be leveraged to provide a higher level of training and technical support to all food regulatory laboratories in the nation, not just to those with FERN funding. Third, it is important to consider expanding the depth and breadth of FERN funding. Laboratories with FERN funding would benefit from additional resources for training and travel as well as more funding for large-sample analytic demands. As noted below, the FDA and the public have benefitted from the investments in FERN to date. The FDA would benefit from the opportunity to expand the FERN network by being able to offer FERN grants to more state and local laboratories.

Therefore, the Subcommittee concludes that the FDA has the opportunity to continue to develop and expand the FERN network. There is a wide range of capabilities and readiness to respond to food emergencies across FERN laboratories. However, with nearly 170 laboratories among the FDA, CDC, USDA-FSIS, and states, there are many more laboratories than FDA and FSIS have funds to support. Therefore, it is important for FDA (and consequently USDA-FSIS) to critically evaluate how FERN’s limited funds can best be utilized to build a sustainable integrated laboratory network that meets public health and regulatory needs within an integrated national food safety system.

6.2 Data Sharing

Question 2: What are the appropriate scientific, analytical, and technical capabilities required to facilitate the sharing of laboratory data between public health and regulatory agencies in a timely and efficient manner to enhance consumer protection?

The Subcommittee has identified a number of concerns regarding the lack of well-designed features as well as poor performance of the existing data-analytics infrastructure.

First, the Subcommittee determined that FERN’s data analytical capability requires an efficient sharing of the range of data types among multiple network partners. Across FERN laboratories, the Subcommittee found an extraordinary dependence on the manual transfer of data from one platform or source to another — even to the point of staff having to resort to using faxes to share data between laboratories followed by a re-keying of data. This lack of seamless data transfer is a function of outdated and inadequate infrastructure resources and discrepancies in technology across laboratories. Needless to say, manual methods of sharing data are prone to significant errors and are highly inefficient. The Subcommittee discovered that this well-

recognized weakness is often discussed in FERN laboratories and is rooted in fundamental differences among partners (i.e., CDC, FDA, USDA-FSIS, state laboratories) as to the need for, or the control of, data access. The fact that this is a long-term systemic problem has only exacerbated the issue and impacted staff morale and organizational commitment to the value of the FERN network.

It appears that the regulatory function is driving the IT/supervisory reaction, causing the creation of an ultra-isolation model that does not have the flexibility to serve other important FDA functions. FDA should take advantage of other large data-sharing opportunities to create some unified data designs. Redesign of IT infrastructure should be done within the context of a long-range strategic planning process as well as within the context of delivering a rapid implementation of near-term fixes. As a redesign of basic system architecture is being implemented, IT considerations should focus early on avoiding a design dominated by a firewall driven exclusively by the regulatory function. Stakeholder engagement should be used in the planning and redesign processes, and these stakeholders must include the state laboratory partners.

The Subcommittee is concerned about the level of connectivity within the network and the ability of state laboratories to participate effectively in the FERN network, including the larger, better-funded laboratories. If the larger more well-supported FERN laboratories are struggling in these functional capacities, where can we expect many of the other, smaller, and less-well-supported laboratories to be? The Subcommittee's sense is that that they are struggling on a more intense level.

The Subcommittee believes that a dramatically new approach to data sharing is required. The need for a data infrastructure that is accessible and efficient is critical to the future value of the FERN network. The current data infrastructure "system" suffers from a combination of factors including its poor design, insufficient maintenance, and lack of perceived importance of what should be considered a vital food safety network that links federal and state partners in combatting foodborne illness. The need for modernization is serious. With the original FERN network design having omitted interoperability, all users miss opportunities to leverage data into good decision making and effective policy. The inability to capture analytical data from FERN laboratories is, in effect, an impediment to full utilization of the FERN-related cooperative agreements.

Therefore, the Subcommittee concludes that it is important that FDA modernize its food safety information architecture to ensure safe and secure transmission of data, even while encouraging and facilitating efficient data sharing and collaboration across the entire network of food safety regulatory laboratories.

6.3 Benefits and Limitations to Funding FERN

Question 3: What are the realized benefits and limitations to these FERN Network, laboratory accreditation, and Laboratory Associations (e.g., APHL, AFDO, AAFCO) cooperative agreements, and how can we improve upon the current utilization of the results of these agreements?

The Subcommittee asserts that FDA's commitment to provide future funding opportunities to FERN, such as the FERN network, accreditation and laboratory association cooperative agreements, will be required to sustain and ensure the realization of a fully integrated multilevel (i.e., federal, state, local, and tribal) food- and feed-testing laboratory network. The Subcommittee found the following realized benefits and limitations:

FERN's Realized Benefits

- Increased expansion of diagnostic capacity through acquisition of specialized equipment, instrumentation and technology.
- Increased capability through specialized training efforts.
- Increased capability through recruitment of scientists/experts.
- Increased food-testing capability through method extension and enhancement studies.
- Increased implementation of standardized methods, procedures, protocols, and quality processes aligned to ISO/IEC 17025:2005 improves overall network efficiency and testing precision.

FERN's Realized Limitations

- Loss of FDA funding would be extremely detrimental to FERN testing capacity and capability.
- Present funding is insufficient to replace/upgrade analytical instrumentation that has exceeded industry-defined life-span.
- When funding is available, the ability to procure equipment easily and in a timely manner remains an administrative challenge.
- The expectation to accommodate unanticipated two- to three-fold increases in testing (sample) volume without a corresponding budget increase for supplies, reagents, and labor costs caused an undue financial burden on participating laboratories.

The Subcommittee's review of the latest-available laboratory progress reports revealed that FDA-ORA's oversight of CAP grantees was effective, as reflected by prior and current achievements and progress to date. However, the Subcommittee also determined that current funding levels can be insufficient to meet a number of critical operational expectations such as accommodating increased volumes of incoming sample testing; negotiating cost-effective service contracts; acquisition of highly sophisticated diagnostic instrumentation; upgrading IT support/resources, including data sharing; and recruiting and retaining specialized and trained laboratory personnel. Generally, FERN CAP laboratories are expected to do more each year but on a flat budget; in some cases the incoming volume of food-/feed-testing samples has tripled (e.g., Richmond laboratory) due to FDA's large-scale surveillance assignments and USDA-FSIS capacity testing, and doing quality and timely analysis on the ever-increasing number of samples thus is not sustainable.

Complicating the sample-volume issue is the inability for long-term planning for analyses by the CAP laboratories due to the inability of the FDA to provide consistent numbers of surveillance samples into the FERN CAP laboratories. The CAP laboratories were prepared to participate in FDA's large-scale surveillance assignments, but these assignments were abruptly cancelled after one year. While this can relieve the financial burden imposed by increased sample volume, it prevents appropriate planning for reagents, equipment and personnel. Recognizing the unpredictable nature of food emergencies, there needs to be better coordination across the agencies to ensure proper planning to address the uneven workload and achieve efficient resource use.

Meanwhile, loss of funding would greatly impact the overall capacity of FERN laboratories. Short-term impacts of funding reduction would include a negative impact on FERN's ability to recruit and retain the highly trained scientists who are crucial for effectively using rapidly advancing diagnostic methodologies. Such a funding loss also would have an adverse short-term impact on recruiting and retaining technicians with requisite high-level technical skills necessary to effectively and safely use complex instrumentation. For example, FERN support accounts for about one-third of overall funding at the Richmond, Va., laboratory, so, if funding were reduced, the chemical program could not be sustained. Long-term impacts of funding reductions would include a negative impact on the U.S. government's ability to enhance and sustain the necessary FDA/FERN assets for proactive food-supply threat surveillance, as well as rapid detection and identification of large-scale food contamination (intentional or accidental).

Among many findings related to FERN funding, the Subcommittee determined that a foundational level of support that would allow the development of core competencies across laboratories would be an excellent model, especially if it included a tiered system to support the development of enhanced laboratory capacity and advanced capabilities. Should such a system be established, it would be ideal if it could be expanded to allow the creation of regional/national centers, which could be the top tier of the network and thus house the top-of-the-line (i.e., most sophisticated and expensive) instrumentation. The tiered organization would help avoid any tendency of a network of individual laboratories from collectively acquiring redundant expensive technical assets/resources.

Therefore, the Subcommittee concludes that FDA's commitment to provide future funding opportunities to FERN will be required to sustain and ensure the realization of a fully integrated multilevel (federal, state, local, tribal) food-testing laboratory network. Such future funding increases should be to increase the depth and breadth of the program, meaning both further increases to the capacity of existing laboratories as well as expanding the numbers of laboratories receiving FERN support. This is an investment that will save money in terms of reduced public health costs as well as costs to industry.

6.4 Public Health Impact

Question 4: How impactful to public health has this building of an integrated laboratory network and promotion of our state laboratories been to date? Explore case studies.

The FERN cooperative agreements have had a multifaceted impact on public health. FDA's ability, through the FERN, to respond to an attack on the nation's food supply, as defined and mandated by U.S. presidential directives, is greatly facilitated by the funding of the cooperative agreement laboratories. These CAP laboratories prepare to react to large-scale intentional food emergencies, to detect, respond to, and assist in recovery from such events. FERN is involved in surveillance assignments to detect related issues. Such assignments can be associated with large political events, responses to potential threats, or smaller, more-specific proactive surveillance of a particular geographic area or food product.

The FERN CAP laboratories have also utilized their abilities to respond to large-scale unintentional food events and have been involved in every large food event in the United States since 2006. FERN responses have included the development and validation of rapid testing methods specific to the requirements of the specific event, providing scarce reagents and/or standards for testing, and testing capacity. For example, FERN provided rapid methodologies, reagents, and capacity for the 2006 *E coli* 0157:H7 outbreak associated with fresh spinach. FERN was also involved in responding to both melamine contaminations (2007 in pet foods and 2008/2009 in milk and proteins), the Deepwater Horizon oil spill of 2010, and the Fukushima Japanese nuclear reactor event of 2011. In these cases, FERN reduced FDA's reaction time by working with FDA to provide improved rapid methods and the analytical capacity and capability to define the scope of the emergency and quickly recover from the event. The ability of FDA and FERN to promote a rapid recovery also has economic benefits; for example, the development of rapid testing methods and testing capacity by FDA and FERN facilitated the reopening of the Gulf waters to commercial fishing after the oil spill in 2010.

Federal funding of FERN, including USDA-FSIS cooperative agreements (FY15 cost of \$3.9 million) and FDA cooperative agreements (FY15 cost of \$10.1 million), resulted in the following outcomes:

FDA and USDA-FSIS

- Nine proficiency testing events were conducted. More than 240 laboratories participated and analyzed samples (e.g., ground pork, dried protein concentrate, mashed potatoes, dog food, apple juice, cheese, and acidified water) for a variety of analytes.
- Annual check sample for the FERN Biosafety Level 3 High Risk Unknown Agent Screening Procedure for Food was provided to 15 FERN laboratories.
- Multi-laboratory validations were performed on five newly developed methods, including:
 - A qualitative screening method for identification of 45 poisons/toxins, and
 - A *Salmonella* rapid screening method.

- Five new Food Defense methods for seven different analytes were evaluated, validated, and approved by the FERN Methods Coordination Committee and added to the repository of FERN methods.

FDA

- Nine training courses provided to more than 150 FERN laboratorians, including:
 - Select Agent training courses,
 - Rapid methodologies training courses including real-time polymerase chain reaction (PCR) methods, and
 - Radiological training courses.
- Continued funding of the FERN Storeroom, providing reagents, supplies and standards to FERN laboratories. These reagents/supplies are typically difficult to obtain on an individual laboratory basis or are kept in bulk in the Storeroom for emergency response. An example of such reagents is the *Clostridium botulinum* toxin detection kits used by both FERN and FDA regulatory laboratories.

USDA-FSIS

- Targeted surveillance of USDA-regulated commodities (e.g., ready-to-eat [RTE] and raw meat and poultry products) at retail via FERN CAP partner laboratories was conducted. Eleven states tested 793 samples for chemical compounds (toxins, poisons, and heavy metals), eight states tested 616 microbial samples for selected agents in FSIS products found at retail locations within their jurisdictions.
- Six laboratories participated in an exercise testing samples for a variety of chemical compounds where the specific contaminant was unknown.
- Eight training courses in food testing and food defense methods were completed. Eighty-five laboratory personnel from state and local food testing laboratories attended courses covering microbiology and chemistry techniques for food analysis.
 - One online course of six modules covering a specific FERN toxin screening method was produced and hosted on the FERN website and has been used by an additional 75 laboratory personnel.
 - Radiochemistry training for the detection of a specific radionuclide was provided to three laboratories with a focus on a streamlined method with reduced testing time.

FERN has also facilitated the coordination and sharing of expertise and essential resources, such as technical capabilities and analytical instrumentation among the partner laboratories. These resources can be applied not just at a federal and national level, but brought to bear on local and state food events. A particular benefit of FERN is its ability to facilitate access within the network to the various specialized instrumentation and analytical capabilities (i.e., radiological

toxicological, microbiological, and chemical analyses) that are distributed unevenly across FERN's geographically dispersed laboratories. An anecdotal example is portrayed in this personal communication from a PhD analytical chemist at a FERN chemistry CAP laboratory:

"We are an agriculture lab in small state; our FDA equipment has exponentially increased our capability and capacity. Right now, over 75% of the equipment in my laboratory is from FDA FERN CAP. In state fiscal year 2015, we processed in excess of 3,000 samples, which included federal, state, and municipal samples, as well as samples from research projects on food safety (nanomaterial exposure) and pollinator decline. The matrices include food, soil/sediment, water, and diverse consumer products. Over 80% of those 3,000 samples involved direct use of our FDA equipment (LC-MS, ICP-MS and GC-MS). Because of this capability and the staff expertise, much of which can be traced to FERN involvement and training, we have become the go-to lab in the state and the region. In short, FERN equipment and involvement has become a critical core component to our operations."²⁰

This ability to coordinate and share resources has a positive impact on public health. For example, the proficiency testing, methods development, training and surveillance activities outlined above greatly improve the preparedness and responsiveness of federal, state, local, territorial and tribal government agencies to food emergencies which, in turn, reduces the impact of such events on public health. Further, the use of common methods and protocols increases the likelihood that a problem across the nation or a region will be detected and the extent of the problem can be assessed more quickly.

It is important to note that FERN could have an even greater public health impact with further investments. For example, FERN was not designed to conduct proactive nation-wide surveillance of the food system. However, engaging FERN more proactively in food safety and foodborne illness surveillance efforts may improve our overall ability to detect, respond to, and mitigate future events. Similarly, implementing the recommendations of this report (e.g., improved data sharing) should also increase FERN's public health impact. As cited in the next section, it is important that metrics that can measure the public health benefit of FERN be developed.

Based on this review, the Subcommittee concludes that FERN has a significant public health impact, and it is vital to maintaining public health preparedness and response. While it is impossible to quantify the health and economic benefits to society from FERN, the examples given in above illustrate the magnitude and breadth of the public health problems that FERN addresses. **Thus, it is important that FDA and USDA-FSIS continue investing in FERN and consider increasing their support.**

6.5 Appropriate Metrics

Question 5: What would be appropriate metrics to measure the effectiveness of these

²⁰ White JC, Vice Director & Chief Analytical Chemist, Connecticut Agricultural Experiment Station.

integration strategies in promoting a national integrated laboratory system?

The Subcommittee asserts that measuring the effectiveness of both FERN and the national integrated laboratory system is critical for informing funding decisions as well as protecting public health. However, it is difficult to determine with great confidence that the current national network of food emergency response laboratories is sufficient and worth the tens of millions of dollars invested to date. Choosing metrics that more specifically assess the public health impact will permit cost-benefit analyses that can show the return on this investment (See examples of metrics in Appendix D).

The effectiveness of a network of laboratories in many respects is built on the effectiveness of the individual laboratories that comprise the network. Laboratory quality systems require evidence of precision, proficiency, reproducibility, accuracy, and documentation. Laboratories rely on their systems both to ensure reliable results, as well as to investigate errors. Accreditation to the relevant ISO standard (in this instance, ISO/IEC 17025:2005) ensures that these quality systems are operating and that the laboratory can provide reliable results for those methods under the scope of accreditation. Laboratory systems depend on both internal and external audits to maintain all elements of accreditation.

Network- or national-level metrics could be developed around the requirements used for individual laboratories under cooperative agreements. Metrics for consideration could include the ability to report equivalent test results throughout FERN. For example, results reported by FERN laboratory 'X' would have the identical value and/or meaning and an equivalent time-to-results as results by FERN laboratory 'Y' in another part of country. Tools to assess this metric could include proficiency testing or exercises to simulate an emergency event. Network-wide standardization and uniformity of testing protocols/procedures, reagent manufacturing, quality control/calibration material under the umbrella of a comprehensive QMS, like ISO/IEC: 17025, could also be used as a measurable metric for accuracy and reproducibility of test results across FERN.

Therefore, the Subcommittee concludes that metrics are important for understanding the impact of FERN. ISO accreditation is considered the gold standard and is an important metric but it is not the only performance metric that should be monitored. FDA and USDA-FSIS in collaboration with state and local laboratories should be charged with developing a broader range of metrics that more directly assess public health impacts, functionality of the network as a system, as well as other goals, such as efficiency.

7. Subcommittee Recommendations

The FERN review Subcommittee, in response to its charge from the Science Board, developed the following set of recommendations in relation to FERN:

Recommendations

1. FERN consists of a group of diverse laboratories, and the focus on developing a basic level of capability/capacity across the network is a worthwhile goal that should be supported by the federal government. The baseline capabilities/capacities needed are not static and funding should be adapted to reflect these changing needs.
2. Efforts to build and sustain capabilities/capacities across FERN need consistent, multi-year funding. FDA should consider additional sources of funding, including cost-sharing or matching requirements for grant programs and recipients, where appropriate and/or possible.
3. While all laboratories should strive to improve capabilities, especially as some techniques become more routine, FDA should develop a plan for FERN that would consider the advantages of a tiered approach designed to avoid unnecessary duplication, for example, of expensive instrumentation across the network. Thus, while all laboratories should share a basic level of functionality, the advanced performance capabilities could be housed primarily or exclusively in regional/national facilities and/or centers with the training and equipment to specialize in certain analytical areas of importance to both the state and the FERN missions, to promote efficient use of existing expertise, equipment, and technical resources.
4. FERN funding agencies (i.e., FDA/ORA, USDA-FSIS) should continue to improve their engagement to discuss areas of common interest and combine efforts to improve testing capacity and capability within and across networks.
5. FDA should develop a technology-management plan to anticipate the eventual replacement of existing instrument platforms that employ newer and more advanced diagnostic methodologies. The plan should be developed in collaboration with the designated specialty laboratories and include: platform selection, acquisition, upgrades/enhancements, along with corresponding technical training for personnel.
6. FDA should assume a holistic approach to addressing the IT and data-sharing needs of FERN partners. There is a strong public health need for an integrated information infrastructure that allows the seamless transmission of data in a secure environment that facilitates rapid analytics. Simply trying to fix the current system is unlikely to achieve this goal; a new system is needed. Such efforts must be guided by a comprehensive plan that is developed through stakeholder engagement (i.e., cooperative laboratories) to meet the needs of an integrated food and feed safety system.
7. FERN leadership should develop clear objectives and adopt a set of metrics for both individual laboratories and the network, with appropriate targets and consensus as to what constitutes success and reflects the objectives.
8. FDA, in collaboration with other federal agencies, should convene an annual conference for the food safety laboratory network to engage scientists in professional education/development activities and facilitate the sharing of information.

9. FERN should have the capacity to support professional travel to conferences and/or for training and development.
10. FDA and its sister federal agencies (i.e., USDA-FSIS, CDC) should work with states on best practices for hiring and retaining scientists who are needed to perform this mission-critical work. Possible collaborators for initiating such efforts include the National Governor's Association and/or National Conference on State Legislatures. These organizations may be able to assist with the identification and/or development of models that can be considered for adoption by states nationally.
11. FDA should regularly communicate with all eligible laboratories to increase public health preparedness and participation in FERN training efforts.

The Subcommittee advises that the recommendations of this report be accepted with the utmost urgency and that our specific recommendations be considered as a means of ensuring the maintenance of a safe and secure food system. The FERN network represents one of the best national investments in improving the responsiveness of our combined federal, state, local and territorial governments; the development of IFSS, and the prevention of foodborne disease.

Appendix A: Subcommittee Charge

Request for Proposal to the Science Board to Be Classified by the Advisory Committee Oversight and Management Staff

The Office of Regulatory Affairs (ORA) is hereby requesting that the Science Board establish a new subcommittee to evaluate the current investments in: (1) the Food Emergency Response Network (FERN) cooperative agreement program, and (2) funding for state laboratories to achieve International Organization for Standardization (ISO) accreditation.

Goal: Ascertain how ORA can advance and establish an effective integrated laboratory network among ORA, FDA Center, and state public health and food- and feed-testing laboratories. Key areas of integration would include methods harmonization; data sharing, data quality, and data reporting; appropriate technical capabilities including IT; the role of proficiency testing and accreditation; and performance metrics.

Background: The mission of FERN is to integrate the nation's multilevel food-testing laboratories to detect, identify, respond to, and recover from a bioterrorism act or public health emergency/outbreak involving the food supply. FERN, established in 2004 by Presidential Directive, provides multiple areas of support to member laboratories, including cooperative agreement funding. Currently, there are 170 laboratory members in FERN, and FDA currently funds, through cooperative agreements, 34 state laboratories: 14 state chemistry laboratories, 15 microbiological laboratories, and 5 radiological laboratories. These laboratories provide increased capability and capacity for laboratory sample analyses of food products for the rapid detection and identification of large-scale food contaminations, intentional or accidental, and have provided these functions for the FDA in most of the large-scale national food events since their initial funding.

FDA/ORA has also invested funds to enhance laboratory capacity/capability and to assist state laboratories in attaining laboratory accreditation to recognized international standards (ISO/IEC 17025:2005). These selected state laboratories are members of FERN and the states are enrolled in the FDA's Manufactured Food Regulatory Program Standards (MFRPS), a set of standards developed by the FDA and selected state program managers that can be used by the states as a guide for continuous improvement for state food manufacturing programs. MFRPS Standard #10 addresses state laboratory services and their quality management systems. Many of the states funded to attain laboratory accreditation also participate in the Food Protection Rapid Response Teams, a program created to address the need for improved and integrated rapid responses to food and feed emergencies.

FDA/ORA also funds a cooperative agreement with the Association of Public Health Laboratories (APHL), the Association of Food and Drug Officials (AFDO), and the Association of Animal Feed Control Officials (AAFCO) to further regulatory laboratory integration. This agreement seeks to facilitate long-term improvements to the national food and animal feed safety system by strengthening multi-disciplinary laboratory collaboration and equivalency, advance laboratory accreditation, and build an integrated laboratory community of state, local, and federal regulatory laboratories.

Scope of Work: The scope of work for this Subcommittee would include the evaluation of these three existing funding agreements and how these agreements or other approaches can best be utilized to build an integrated laboratory network among public health food- and feed-testing laboratories. Specifically, how can the Agency continue to build a sustainable integrated laboratory network that meets the public health and regulatory needs under an integrated national food safety system? Also, the technical areas of data sharing, proficiency testing, method harmonization, quality and reporting of analytical results would be assessed so as to provide recommendations to facilitate the rapid and efficient interchange of laboratory results in an integrated laboratory network.

Questions for the Board

- 1) How can we further promote and build an integrated laboratory network among the food regulatory laboratories of ORA, FDA Centers, USDA's FSIS, and state health departments as part of developing a stronger system of mutual reliance in the food and feed program?
- 2) What are the appropriate scientific, analytical, and technical capabilities required to facilitate the sharing of laboratory data between public health and regulatory agencies in a timely and efficient manner to enhance consumer protection?
- 3) What are the realized benefits and limitations to these FERN Network, laboratory accreditation, and Laboratory Associations (e.g., APHL, AFDO, AAFCO) cooperative agreements, and how can we improve upon the current utilization of the results of these agreements?
- 4) How impactful to public health has this building of an integrated laboratory network and promotion of our state laboratories been to date? Explore case studies.
- 6) What would be appropriate metrics to measure the effectiveness of these integration strategies in promoting a national integrated laboratory system?

Appendix B: Schedule of Interviews with and Presentations to the Subcommittee

October 9, 2015, presentation:

APHL/AFDO
Shari Shea
Ron Klein
Nancy Thiex
Yvonne Salfinger

October 23, 2015, presentation:

USDA/FERN
Randy Layton
Ron Blakely

November 17, 2015, presentation:

FDA/ORO Office of Partnerships presentation on cooperative agreements
Erin Woodom-Coleman (FDA)
FDA FERN Overview
Don Burr (FDA)

November 30, 2015, presentation:

FDA eLEXNET Overview
JeanPaul Mivoyel (FDA)
Solomon Tadele (FDA)
Rahsaan Tabb (FDA)

January 11-12, 2016, site visit:

Commonwealth of Virginia, Division of Consolidated Laboratory Services – Richmond
Denise Toney – Director
Angela Fritzinger – Deputy Director
Ed Shaw
Chris Waggener
Shane Wyatt

February 24, 2016, interview:

Maria Ishida, New York Dept. of Agriculture
Andrew Cannons, Florida Dept. of Health

March 2, 2016, interview:

Michael Hydock (Pennsylvania Dept. of Agriculture)
Robyn Atkinson (Utah – Public Health Lab)
Phil Zillinger (Indiana State Dept. of Health)
Judy Lovchik (Indiana State Dept. of Health)

Appendix C: Questions for Laboratory Site Visits

The FDA Science Board Subcommittee on the Food Emergency Response Laboratory Network (FERN) has been charged with ascertaining how FDA's Office of Regulatory Affairs (ORA) can advance and establish an effective integrated laboratory network among ORA, USDA-FSIS, FDA Centers, and state public health and food- and feed-testing laboratories. The deliverable for the Subcommittee is an evaluation/recommendations report that addresses the five objectives outlined below. For each objective, the Subcommittee identified a series of questions to be asked of laboratory staff during the site visits.

Objective 1. Evaluate existing cooperative agreements with FSIS, APHL, AFDO, and AAFCO to further regulatory laboratory integration. Questions to address:

1. Describe the funding sources you receive for regulatory laboratory activities. How much of what you do is funded by the Federal versus the State governments?
2. Describe your relationships/cooperative agreements with FSIS, APHL, AFDO, and AAFCO.
3. Does each agreement have a distinct 'scope or task'? Or, do they overlap?
4. Can you describe the specific activities for each of the funding streams?
5. Can you describe some of the benefits since receiving this funding? Specifically, has the funding assisted you in expanding the scientific capacity of your operation? If so, how?
6. What are the remaining areas needing improvement?
7. Describe your experience and status with your laboratory accreditation process?
8. Do you have recommendations to improve the grant/funding/procurement process?
9. Do you have any suggestions to maximize the use of funds?
10. What services, activities or initiatives would be impacted if funding were no longer available?
11. Do you feel your experience/perspective is representative of all laboratories in the network? If not, how do you think it differs?

Objective 2. Identify how the Agency can continue to build a sustainable integrated laboratory network that meets the public health and regulatory needs under an integrated national food safety system. Questions to address:

1. Can you describe the network's configuration and where this laboratory fits in?
2. What are your thoughts regarding strategies to 'sustain' the network?
3. How has public health benefited since the creation of the integrated laboratory network?
4. How does the integrated laboratory network extend/expand the Agency's scientific capacity?
5. What could the Agency be doing to strengthen scientific capacity across the network?

Objective 3. Assess technical areas of data sharing, proficiency testing, method harmonization, quality and reporting of analytical results. Questions to address:

1. How comfortable are the laboratory staff with the equipment they have?
2. Can the proficiency testing program be improved?
3. Has method harmonization impacted competency assessment of testing personnel?
4. What is the quality of and consistency of reporting of analytical results across the network?

5. Are the network activities improving these capabilities? Do you have any thoughts about how to further improve them?

Objective 4. Provide recommendations to facilitate the rapid and efficient interchange of laboratory results in an integrated laboratory network. Questions to address:

1. What's the current status of data sharing between FERN laboratories?
2. What's the current status of data sharing between FERN laboratories and FDA?
3. What are the obstacles?
4. Do you have recommendations for improving the exchange of laboratory results?

Appendix D: Examples of Metrics Used by FERN and Various Other Laboratory Organizations

FDA FERN Cooperative Agreement Metrics

- 1) CAP program metrics that are required by Cooperative Agreement Program guidance (2 Code of Federal Regulations Part200 [2 CFR 200]):
 - a. Quarterly reports including project information and budget information
 - b. Final reports
 - c. Monthly calls with project officers
- 2) Equipment:
 - a. Operational status of equipment loaned under the cooperative agreement
 - b. Are service contracts maintained on all equipment loaned under the cooperative agreement?
 - c. Are instruments operational greater than or equal to 90 % of the time?
 - d. Reporting use/impact of equipment on routine laboratory operations (non-FERN-directed activities) including:
 - i. Improvement of capacity/throughput for normal laboratory sample analysis
 - ii. Impact of any expanded capability resulting from provided instrumentation
 - iii. Use of equipment to support routine state laboratory sample analysis and/or emergency outbreak sample analysis
- 3) Participation by CAP laboratories in Proficiency Tests (PT) and check sample programs
 - a. Laboratories report participation and pass/fail results for proficiency tests that they participated in during the reporting period
 - i. PT sample sources: FERN, AOAC, other FDA (non-FERN), LRN, etc.
 - ii. At this time, there is no minimum requirement for numbers of PTs expected to be performed during each reporting period
- 4) Cooperative Agreement-Funded Project Accomplishments
 - a. Report work/outcomes of any method development or matrix extension projects conducted under the award and anticipated impact of this work, including submissions of methods for consideration to become official FERN methods that are available to all FERN laboratories
 - b. Report any state-initiated sampling programs conducted and funded through the award, including specific sample information:
 - i. Numbers of samples analyzed
 - ii. Products analyzed
 - iii. Methods used
 - iv. Results
 - v. Provide full analytical worksheet packages as requested
 - vi. Report any state or FDA regulatory action based on results from these state-initiated surveillance sampling programs

- 5) FDA Directed Sampling:
 - a. Report numbers of samples analyzed and results of any FDA directed or provided samples
 - b. Provide official analytical worksheet data packages to be evaluated for potential FDA regulatory action based on sample results
 - c. Track percentages of worksheets that meet FDA Center SME technical review approval requirements to support regulatory action
 - d. Document any possible FDA regulatory action based on state data reports
 - e. Document any issues with data worksheets that may prevent FDA use of that data to ensure issues are addressed and corrected for future data submissions
- 6) Responsiveness:
 - a. What is the measured response time of the CAP laboratory to activations or requests?
 - b. Percentage of conference call/meetings attended by CAP laboratory during the reporting period
 - c. Did CAP laboratory notify the FERN National Program Office (NPO) if capability or capacity was down for a significant period of time due to vacancies or equipment malfunctions?
- 7) Outreach:
 - a. CAP laboratories assisting non-funded FERN laboratories with training, sample analysis, proficiency test preparation, etc.
 - b. Participation in activities supporting state Rapid Response Team programs
 - c. Participation in Partnership for Food Protection (PFP) activities:
 - i. Mutual Reliance Programs
 - ii. Working groups
 - d. Participation in FSMA implementation support activities
 - e. List of publications resulting from FERN supported work
 - f. List of meeting presentations resulting from FERN supported work

DRAFT FSIS Metrics for FERN CAP Projects

Since the CAP laboratories work mostly on individually proposed projects, the most common metric used for an individual laboratory in the FSIS CAP program is “completed”/“not completed.”

Selected measures of laboratory’s acceptable progress in the program:

- 1) Was the proposed project completed? Was project result published, presented, submitted as validated method to FERN, FDA, or USDA-FSIS?
- 2) Did the laboratory increase in capacity or capability and is this reflecting the Laboratory Database (LabDIR) information on the FERN website (www.fernlab.org)? Example: Laboratory A increased in capability by verifying it could test for ricin in foods. This would be reflected in the LabDIR as a new capability.
- 3) Participation by CAP laboratories in the PT and check sample programs.

- 4) Participation by CAP laboratories in the training courses. The numbers of students a state laboratory has sent to training courses might speak to their increases in capacity/capability as well.
- 5) CAP program metrics that are required by Cooperative Agreement Program guidance (2 CFR 200):
 - a. Quarterly reports, including project information and budget information
 - b. Final reports
 - c. Monthly calls with project officers
- 6) Completion of surveillance samples for food defense analytes. This metric is new for this year for USDA-FSIS. The goal is at least 250 samples for each USDA-FSIS CAP laboratory. This metric will be a pass/fail or incomplete “grading,” until it is determined that it should be measured differently.
- 7) Capability and Capacity Exercise. USDA-FSIS CAP laboratories have participated in an exercise to demonstrate either their capacity or capability — as recorded in the LabDIR — through a functional exercise in which laboratories analyze samples supplied by USDA-FSIS. In the future, the USDA-FSIS CAP program could track time to reporting, number correct, number completed, and/or number of different analyses performed.

Metrics that have been used for the FERN program as a whole:

- 8) The FERN program instituted a tiering program that “grades” FERN participating laboratories based on the information in the LabDIR system. The tier system scores individual laboratories’ capabilities in the three testing disciplines (microbiology, chemistry, and radiochemistry), based on the information they submit to the LabDIR. Overall scores are compared and laboratories are divided into high, medium, and low categories in a system that only the FERN National Program Office can see. This system is useful for quick determination of laboratories’ capabilities in individual disciplines.
- 9) The FERN program, in general, has tracked the number of training courses offered and the number of participants from individual laboratories, but no goal numbers have been established concerning participation by individual laboratories. The numbers of students a state laboratory, or the number of different laboratories that have sent participants to training courses might speak to the increase in capacity/capability of the network. The training program does try to fill all available seats in the offered courses, regardless of CAP status for the laboratories.
- 10) Participation by FERN laboratories in the PT and check sample programs are tracked, but no goal numbers concerning participation in individual events have been established. The PT program does have its own metric of providing one PT per quarter, alternating between microbiology and chemistry.

Metrics that have been considered, but not implemented, for the CAP program:

- 1) Number of new matrices validated by a laboratory for a particular method.
- 2) Completion of a method validation with submission of the data packet to the FERN Methods Coordination Committee.

- 3) Surveillance samples: 400 per year for tier-level-one laboratories, and 250 per year for tier-level-two laboratories. Analysis can be microbiology, chemistry, and/or radiochemistry.
- 4) Include the ability of CAP laboratories to run USDA-FSIS *Microbiology Laboratory Guidebook* (MLG) and *Chemistry Laboratory Guidebook* (CLG) methods as part of the LabDIR information on the FERN website. This may increase capacity and capability of the laboratories as well as provide food safety surge capacity to USDA-FSIS.
- 5) Include the status of CAP laboratories in terms of testing methods being designated either “equal to” or “same as” those of USDA-FSIS.

Metrics considered but not implemented:

- 1) Number of trained analysts for a specific method in a state laboratory (regardless of CAP status). The program did not have enough resources to train everyone at every laboratory. Also, the staff turn-over at state laboratories meant this could never be completed. Some state laboratories just do not participate in the training or are hindered by state policies from attending training.
- 2) Correct results reported for PT samples, pass/fail criteria (regardless of CAP status). States that report incorrect PT results are contacted for follow up. However, no pass/fail or grading criteria is recording in the system. It was determined that if laboratories were graded, then laboratories would be less likely to participate, especially following a failing set. It has also been reported by the states that participating in a graded program for analytes outside of their accreditation scope would be a hindrance to their participation. We would much prefer they participate and practice an analysis that they do not run on a regular basis.
- 3) Include the ability of CAP laboratories to run FSIS MLG and CLG methods as part of the LabDIR information in the FERN website. The may increase capacity and capability of the laboratories as well as provide food safety surge capacity to FSIS.

Metrics no longer used/supported, mainly due to lack of resources:

- 1) Participation of FERN laboratories, regardless of CAP status, in the Annual Training Conference with scientific sessions for specific disciplines as well as regional discussion groups
- 2) Participation in regional meetings led by the National Program Office and regional coordinator to increase communication between laboratories on regional basis
- 3) Participation in desktop exercises through regional coordination that demonstrated proficiency in responses to an event and FERN activation

*Selected Laboratory Response Network (LRN) Metrics — CAPABILITY 12: Public Health Laboratory Testing**

Public health laboratory testing is the ability to conduct rapid and conventional detection, characterization, confirmatory testing, data messaging and reporting, investigative support, and laboratory networking to address actual or potential exposure to all-hazards.²⁶⁰ Hazards include chemical, radiological, and biological agents in multiple matrices that may include clinical samples, food, and environmental samples (e.g., water, air, and soil).²⁶¹ This capability supports routine surveillance, including pre-event²⁶² and post-exposure activities.²⁶³

This capability consists of the ability to perform the following functions:

Function 1: Manage laboratory activities

Function 2: Perform sample management

Function 3: Conduct testing and analysis for routine and surge capacity

Function 4: Support public health investigations

Function 5: Report results

Function 1: Manage laboratory activities

Manage and coordinate communications and resource sharing with the jurisdiction's network of human, food, veterinary, and environmental testing laboratory efforts in order to respond to chemical, biological, radiological, nuclear, explosive, and other public health threats. This function consists of the ability to perform the following task:

Task 1: Exchange information and data with laboratories and laboratory networks within the jurisdiction. *(For additional or supporting detail, see Capability 6: Information Sharing.)*

Performance Measure(s) (this is a partial list)

This function is associated with the following CDC-defined performance measures:

Measure 1: Time for sentinel clinical laboratories to acknowledge receipt of an urgent message from the CDC Public Health Emergency Preparedness (PHEP)-funded Laboratory Response Network biological (LRN-B) laboratory

* Note: This LRN material is necessarily incomplete due to length of the original document and includes only selected metrics. The complete document is available online (at <https://www.cdc.gov/phpr/capabilities/capability12.pdf>) and is thus in the public domain; however, it is used here with permission. The original superscript reference citation numbers are retained for reference purposes for the readers' convenience, but the actual references are not listed because of space limitations in this report of the FERN Subcommittee.

- Start time: Time CDC PHEP-funded laboratory sends urgent message to first sentinel clinical laboratory
- Intermediate stop time: Time at least 50% of sentinel clinical laboratories acknowledged receipt of urgent message
- Intermediate stop time: Time at least 90% of sentinel clinical laboratories acknowledged receipt of urgent message
- Stop time: Time last sentinel clinical laboratory acknowledged receipt of urgent message

Planning (P)

P1: (Priority) Written plans must include at a minimum the identification of laboratories and laboratory networks within the jurisdiction^{264,265} as well as procedures for interaction with the following laboratories and groups:

- LRN-B reference laboratories within the jurisdiction
 - Support and ensure LRN-B reference laboratory communication with all LRN-B sentinel and all other LRN-B reference laboratories within the jurisdiction
- Federal laboratory networks and member laboratories within the jurisdiction
 - e.g., the Food Emergency Response Network, National Animal Health Laboratory Network, and the Environmental Response Laboratory Network

P2: (Priority) Written plans must include the following elements:

- Documented procedures for contacting sentinel laboratories in the event of a public health incident²⁶⁶

P3: Written plans should include processes and protocols for continuity of operations (e.g., Continuity of Operations Plan or Annex) for chemical laboratory, radiological laboratory, biological laboratory and select agents consistent with federal guidelines, which are updated on an annual basis.²⁶⁷ Continuity of Operations should include not only the ability to conduct testing on unknown and unusual agents but also routine testing such as the assurance of newborn screening.²⁶⁸ Plans should address, but are not limited to the following elements:

- Laboratory maintenance of redundant utilities supplies for testing and support areas for short-term duration (i.e., 72 hours) in case of localized infrastructure failure
- Formal or informal agreements in place with other agencies to take over critical testing
- Staff illness
- Equipment failure

Skills and Training (S)

S1: Laboratory staff should be aware of current national policy and practice. Maintaining this understanding can be accomplished through sending one chemistry representative, one radiological representative, and one biological representative from the jurisdiction to the LRN national meeting. Also, it is recommended if possible,

but not required, that each LRN Laboratory Director also attend LRN national meetings.

- S2:** At least one individual on staff should be capable of coordinating personnel safety and methods trainings, plans, and guidance, and outreach to sentinel and first responder communities throughout the jurisdiction. These staff should coordinate biological, chemical, and radiological activities. Depending on the jurisdiction, these positions may be filled by one or more individuals with the appropriate experience and training to perform the duties.

Equipment and Technology (E)

- E1:** Have or have access to a database of current contact information for identified LRN-B advanced sentinel laboratories, LRN-B reference laboratories, LRN-R laboratories (if program funds become available), and LRN-C laboratories in the jurisdiction, as well as laboratories both inside and outside the jurisdiction that work with the jurisdictional public health agency.²⁶⁹

Function 2: Perform sample management

Implement LRN-established protocols and procedures where available and applicable [and other mandatory protocols such as those for the International Air Transport Association (IATA) and the U.S. Department of Transportation (DOT)] for sample collection, handling, packaging, processing, transport, receipt, storage, retrieval, and disposal.

Tasks

This function consists of the ability to perform the following tasks:

- Task 1:** Handle, package, and transport samples following established IATA/DOT and laboratory-specific protocols.
- Task 2:** Maintain forensic chain-of-custody throughout the sample-management process.

Performance Measure(s)

This function is associated with the following CDC-defined performance measures:

- Measure 1:** Percentage of LRN clinical specimens without any adverse quality assurance events received at the CDC PHEP-funded LRN-B laboratory for confirmation or rule-out testing from sentinel clinical laboratories
- Numerator: Number of LRN clinical specimens without any adverse quality assurance events received at CDC-PHEP-funded laboratory for confirmation or rule-out testing from sentinel clinical laboratories
 - Denominator: Total number of LRN clinical specimens received at CDC PHEP-funded laboratory for confirmation or rule-out testing from sentinel clinical laboratories
- Measure 2:** Percentage of LRN non-clinical samples without any adverse quality assurance

events received at the CDC PHEP-funded LRN-B laboratory for confirmation or rule-out testing from first responders

- Numerator: Number of LRN non-clinical samples without any adverse quality assurance events received at CDC PHEP-funded laboratory for confirmation or rule-out testing from first responders
- Denominator: Total number of LRN non-clinical samples received at CDC PHEP-funded laboratory for confirmation or rule-out testing from first responders

Measure 3: Ability of the CDC PHEP-funded LRN-C laboratories to collect relevant samples for clinical chemical analysis, packaging, and shipping those samples

- Sample Collection, Packing and Shipping Exercise Results (Pass/Did not pass)

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

Planning

- P1:** Written plans should include procedures and protocols for sample collection, triage, packaging, shipping, transport, handling, storage and disposal. Sample collection procedure should address 24/7 contact information and submission criteria.
- P2:** Written plans should address transportation security and, at a minimum:²⁷⁰
- LRN-B: Select Agent and Toxin Regulations
 - LRN-C: Chemical Hygiene Plan
 - LRN-R: Radiation Safety and Security Plan, if program funds become available
- P3:** Written plans should include a protocol for chain of custody. Forensic chain of custody procedures must meet the minimum evidentiary control procedure requirements established by federal partners such as the Federal Bureau of Investigation (e.g., LRN, Integrated Consortium of Laboratory Network).²⁷¹
- P4:** Written plans should include procedures in place to maintain sampling and/or shipping supplies stock, or demonstrate ability to procure or have access to supplies 24/7.²⁷²

Skills and Training (this is a partial list, hence the non-continuous numbering)

- S1:** (**Priority**) Laboratory staff responsible for sample management must maintain certification of laboratory personnel in a shipping and packaging program that meets national and state requirements (e.g., Sample Collection, Packing and Shipping; ShipPack).
- S4:** Document training on practices for personnel safety while managing samples, with documentation updated a minimum of once per year, for laboratory personnel.
- S5:** Maintain appropriate regulatory requirements, including the following elements:
- A valid Select Agent Registration Number (LRN-B Advanced Reference laboratories only); Standard Reference laboratories are encouraged, but not

required, to maintain select agent registration to support broader public health response

- A valid U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Veterinary Services shipping permit (LRN-B laboratories only)
- Nuclear Regulatory Commission or state licensing requirements (LRN-R laboratories only, if program funds become available)

Function 3: Conduct testing and analysis for routine and surge capacity

Perform, or coordinate with the applicable lead agency, testing of chemical, biological, radiological, nuclear, and explosive samples, utilizing CDC-established protocols and procedures (e.g., LRN), where available and applicable, to provide detection, characterization and confirmatory testing to identify public health incidents. This testing may include clinical, food, and environmental samples.

Tasks

This function consists of the ability to perform the following tasks:

Task 1: Provide LRN-B reference-level testing in clinical, food, and environmental samples for both rapid and conventional methods.

Task 2: Conduct chemical laboratory testing following LRN-C testing methods.

Task 3: Conduct radiological and nuclear laboratory testing following LRN-R (if program funds become available) testing methods.

Performance Measure(s) (this is a partial list)

This function is associated with the following CDC-defined performance measures:

Measure 1: Proportion of LRN-C proficiency tests (core methods) successfully passed by CDC PHEP-funded laboratories

- Numerator: Number of LRN-C core methods successfully proficiency tested by the CDC PHEP-funded laboratory
- Denominator: Total number of LRN-C core methods for which the CDC PHEP-funded laboratory is qualified to test

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

Planning

P1: (Priority) Written plans should include the following considerations for surge capacity:

- Options to optimize procedures based on regular and surge personnel, equipment, and facility resources for short-term (e.g., days) and long-term (e.g., weeks to months) response efforts

- Triage policies that address how the laboratory will manage surge testing, which may include:
 - Referral of samples to other jurisdictional laboratories
 - Prioritization of testing based upon sample type
 - Prioritization of testing based upon risk or threat assessment
 - Contingencies to assure newborn screening in a surge situation. Newborn screening can be assured by memoranda of agreement or contracts with commercial vendors²⁷³

- P2:** **(Priority)** Written plans should include preventative maintenance contracts and service agreements in place for equipment and instruments utilized in LRN protocols, procedures, and methods at a minimum. Plans should also include protocols to ensure that equipment and instruments utilized in LRN protocols, procedures, and methods have been inspected and/or certified according to manufacturer’s specifications.
- P3:** Written plans should include a process that provides guidance for referring suspicious samples (e.g., from sentinel laboratories or first responders) to an LRN reference laboratory.
- P4:** Written plans should include considerations for supply accessibility, including identifying multiple vendors for critical commercially available reagents/supplies.
- P5:** Written plans should include processes and procedures to operate at expanded laboratory capacity for surge events and incidents.

Skills and Training

- S1:** **(Priority)** Laboratories participating in radiological or nuclear testing must attain LRN-R (if program funds become available) Proficiency Testing Program Qualified status for all analysis methods transferred by LRN-R through the following:
 - Attending LRN–R training, if program funds become available
 - Completing the associated laboratory validation exercise, demonstrating performance and precision according to the minimum standards for each analytical method.
- S2:** **(Priority)** LRN-B reference laboratories must attain competency for LRN-B testing methods by having the ability to test for all agents/sample types/tests listed in the high risk environmental sample testing algorithm posted on the secure LRN website.
- S3:** **(Priority)** All LRN Laboratories (excluding LRN-B sentinel laboratories) must maintain the competency to pass LRN proficiency tests.
- S4:** **(Priority)** Laboratories participating in chemical testing must attain LRN-C Proficiency Testing Program Qualified status, through the ability to perform the following:
 - Core LRN-C methods testing, for all Level 1 (surge capacity laboratories only) and Level 2 analysis methods transferred by CDC. Core LRN-C methods are identified on the LRN website and updated at least annually.
 - Validation and qualification of at least one new analysis method per year is

required.

- S5:** Document LRN methods training, with documentation updated a minimum of once per year, for personnel that regularly perform LRN methods, as well as staff identified as surge-capacity personnel. Documentation should include training date and manner of delivery (e.g., formal training or “train the trainer”). Formal training: CDC courses and CD- or DVD-based courses, with completion verified by a formal demonstration.
- S6:** If possible, (but not required) send one chemical, one radiological, and one biological laboratory representative to meetings focused on technical competencies.
- S7:** Send at least one chemistry representative from each LRN-C Level 1 surge laboratory to participate in the bi-annual LRN-C Level 1 surge capacity meeting.
- S8:** Document safety training, with documentation updated a minimum of once per year, for personnel that regularly perform LRN testing, as well as staff identified as surge-capacity personnel. Documentation should include training date and manner of delivery (e.g., formal training or “train the trainer”). Formal training: CDC courses and CD- or DVD-based courses, with completion verified by a formal demonstration.
- S9:** Attain accreditation for LRN-C clinical testing, at a minimum, via an appropriate accreditation body [e.g., at a minimum, Clinical Laboratory Improvement Amendments (CLIA), or College of American pathologists (CAP)]
- S10:** Attain accreditation for LRN-B clinical testing, at a minimum, via an appropriate accreditation body (e.g., at a minimum, CLIA or CAP)
- S11:** Attain accreditation for LRN-R clinical testing, at a minimum, via an appropriate accreditation body, if program funds become available (e.g., at a minimum, CLIA or CAP)

Equipment and Technology

- E1:** Have or have access to a biosafety level 3 laboratory.
- E2:** Laboratory owns and maintains at least one instrument each for rapid nucleic-acid detection and antigen-based detection and instruments are listed in the current equipment list (which is updated annually on the secure LRN website).
- E3:** Level 2 laboratories own and maintain equipment for at least one instrument each for detection of LRN-C agents, that are listed in the current equipment list (which is updated annually on the secure LRN website), to demonstrate qualified status for the listed Level 1 (surge capacity laboratories only) and Level 2 methods.
- E4:** Level 1 laboratories must obtain and maintain additional support equipment and supplies listed in each method.
- E5:** LRN-R laboratories (if program funds become available) own and maintain equipment and maintain staff for at least one instrument each for detection of LRN-R agents that are listed in the LRN-R Equipment List (which is updated annually on the secure LRN website).
- E6:** Maintain inventory or reliable sources of testing material that includes CDC/LRN provided analyte-specific test kits, ancillary reagents, control strains, calibration

- standards, and laboratory supplies required to run LRN analytical methods.
- E7:** Have or have access to equipment necessary for performing LRN assays.

Function 4: Support public health investigations

Provide analytical and investigative support to epidemiologists, healthcare providers, law enforcement, environmental health, food safety, and poison control efforts to help determine cause and origin of, and definitively characterize, a public health incident.

Tasks

This function consists of the ability to perform the following tasks:

- Task 1:** Establish and maintain the ability to provide analytical support for investigations with first responders and other health investigation community partners. *(For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation.)*
- Task 2:** Provide investigative consultation and technical assistance to jurisdictional health departments, first responders, and other health investigation community partners regarding sample collection, management, and safety. *(For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation.)*

Performance Measure(s) (this is a partial list)

This function is associated with the following CDC-defined performance measures:

- Measure 1:** Time to complete notification between CDC, on-call laboratorian, and on-call epidemiologist
- **Start time:** Date and time that CDC Department of Emergency Operations official began notification of on-call laboratorian
 - **Stop time:** Date and time on-call epidemiologist (after receiving notification from on-call laboratorian) notifies CDC Department of Emergency Operations that notification drill is complete

Resource Elements (this is a partial list)

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

Planning (this is a partial list)

- P1:** Written plans should include processes to coordinate activities, gain assistance from, and/or share data with the following group:
- Epidemiologists who are at the interface between clinicians/hospitals, health departments, and the laboratory *(For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation.)*

- Veterinary diagnostic or food safety laboratories, if applicable, which serve animal populations and investigate food products (*For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation.*)

Function 5: Report results

Provide notification of laboratory results and send laboratory data to public health officials, healthcare providers, and other institutions, agencies, or persons as permitted by all applicable laws, rules, and regulations.

Tasks (this is a partial list)

This function consists of the ability to perform the following tasks:

Task 1: Notify appropriate public health, public safety, and law enforcement officials (24/7) of presumptive and/or confirmed laboratory results from clinical, food, or environmental samples that involve a chemical, radiological, or biological threat agent. (*For additional or supporting detail, see Capability 6: Information Sharing.*)

Performance Measure(s)

At present this function is associated with the following CDC-defined performance measures:

Measure 1: Time for CDC PHEP-funded laboratory to notify public health partners of significant²⁷⁶ laboratory results

- **Start time:** Time CDC PHEP-funded laboratory obtains a significant laboratory result
- **Stop time:** Time CDC PHEP-funded laboratory completes notification of public health partners of significant laboratory results (i.e., time when last public health partner was notified, if partners were not notified simultaneously)

Resource Elements (this is a partial list)

Planning

P1: Written plans should include processes and protocols to ensure proper security and maintenance of records management system.^{277,278} (*For additional or supporting detail, see Capability 6: Information Sharing.*)

P2: Written plans should include data-exchange processes, as permitted by all applicable laws, rules and regulations, with law enforcement, public safety, and other agencies with roles in responding to public health threats. These processes should address data security and inappropriate disclosure of information.^{279,280,281} (*For additional or supporting detail, see Capability 6: Information Sharing.*)

P3: Written plans should include notification procedures that detail the process of reporting results that are suggestive of an outbreak or exposure to appropriate health investigation partners utilizing secure contact methods per the LRN-B, LRN-C, or LRN-R

(if program funds become available) Notification Policy and/or laboratory-specific policies.²⁸² (For additional or supporting detail, see *Capability 3: Emergency Operations Coordination and Capability 6: Information Sharing.*)

Equipment and Technology

- E1: (Priority)** Each LRN laboratory will build or acquire and configure a jurisdictional Laboratory Information Management System (LIMS) with the ability to send testing data to CDC according to CDC-defined standards. (This will reduce the duplicate entry into multiple data exchange systems (i.e., having to put data into results messenger or other data exchange systems to be able to send to CDC, public health partners, and other submitters).^{283,284}
- E2:** Ensure at least one member of each laboratory area represented in the jurisdiction (LRN-B, LRN-C, LRN-R, if program funds become available) has a working digital certificate for access to electronic results-reporting systems.
- E3:** Have or have access to at least one working computer for access to LRN and partner electronic reporting systems.
- E4:** Have or have access to a mechanism (e.g., automated, electronic, or paper) for reporting results to LRN-B, LRN-C and LRN-R (if program funds become available), at a minimum, as appropriate.²⁸⁵

Associations (APHL, AFDO, AAFCO) Cooperative Agreement Draft Metrics (3/16/16)

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
Section # 1								
1	1.2- Online resource repository	Grant	Awareness of APHL Accreditation Resources website	APHL	Count from website Accreditation Resources (http://www.aphl.org/aphlprograms/food/laboratory-accreditation/Pages/Accreditation-Resources.aspx)	Yes	With required reports to FDA	Maintain or increase in # of views of accreditation resources website
2	1.2- Online resource repository	Grant	Awareness of Accreditation Resource Repository	APHL	Count from website: Resources for Governmental Food and Animal Feed Laboratories	Yes	With required reports to FDA	Maintain or increase in # of views of resource repository
3	1.2- Online resource repository	Grant	Active work by the Associations to ensure updated resources	APHL	Count from website for Accreditation Resources and Resources for Governmental Food and Animal Feed Laboratories	Yes	With required reports to FDA	# of new/updated documents added to resource webpage and repository annually.
4	1.3- Accreditation discussion board	Grant	Use of Discussion Board	APHL	Count from Discussion Board SharePoint site: Count # Topics/Unique threads	Yes	With required reports to FDA	Maintain or increase in # of topics/ unique threads on APHL Discussion Board
Section #2								
5	2.1- Sampling and sample handling guidelines	Grant	Active work by the Associations to complete Guidance on Obtaining	AAFCO	Status of GOODSamples (completed)	Yes	Status report: Y03 completion of	GOODSamples completed.

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
			Defensible Samples (GOODSamples)				GOODSamples	
6	2.1 Sampling and sample handling guidelines	Grant	Active work by the Associations to market GOODSamples	AAFCO	Marketing activities via APHL, AFDO, and AAFCO	Yes	Marketing activities with reports to FDA	GOODSamples will be available and marketed through Association websites, newsletters, email and similar venues.
7	2.1- Sampling and sample handling awareness training	Grant	Providing awareness training on the principles of defensible sampling and Theory of Sampling (TOS)	AAFCO	Listing of seminars, dates and venues of awareness training on the principles of defensible sampling and Theory of Sampling (TOS)	Yes	With reports to FDA	Laboratory managers and regulatory program staff will be aware of a shift in paradigm for sample collection, TOS and the GOOD Samples document.
8	2.1- Sampling and sample handling	Impact	Adoption of sampling practices based upon <i>GoodSamples</i>	survey	Survey assessing use of GOODSamples and subsequent changes in practice (would be nice to have baseline practices, but can still assess changes/improvements in practice via self-reporting)	No	Annual	GOODSamples practices are incorporated into regulatory programs which participated in Pilots.

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
9	2.2- Web-based Subject Matter Expert (SME) registry	Grant	Convening and maintaining a web-based SME registry	AFDO	Counts from website- http://www.afdo.org/sme	Yes	Annual	# registered SMEs annually by area of expertise; # of website hits on SME database.
10	2.2- Web-based Subject Matter Expert (SME) registry	Impact	Value of SME registry	AFDO research	Survey of SMEs and laboratories/programs www.afdo.org/sme (specifically Food Laboratory, Laboratory Accreditation, Pet Food Testing, Sampling categories)	No		SME contacts resulting in assistance to a program or laboratory
Section #3								
11	3.1- Marketing and outreach efforts around eLEXNET	Grant	# of eLEXNET users running reports	FDA	FDA as part of CAP	Yes	With required reports to FDA	Increase in number of users running reports in eLEXNET
12	3.3- Standard data elements. Identify existing vocabulary and data messaging standards and develop standards specific to food and feed-testing laboratory reporting	Grant	Availability of a common set of data elements and messaging standards	APHL, FDA	APHL developed product	Yes	One time	Availability of a common set of data elements and messaging standards
13	3.3- Standard data elements.	Grant	# of laboratories adopting a	APHL, FDA				Increase in the # of laboratories

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
	Identify existing vocabulary and data messaging standards and develop standards specific to food and feed-testing laboratory reporting		common set of data elements and messaging standards					adopting a common set of data elements and messaging standards
14	Overall aim of data sharing	Impact	Action taken based on data in eLEXNET accredited scopes	FDA and/or State Regulators (AFDO)	Anecdotal information from FDA or AFDO members	No		Action taken based on data in eLEXNET
Section #4								
15	4.5- Community building and networking	Grant	Active work by the Associations to ensure updated resources in Topical Index for Laws and Guidance	AFDO	Counts of #documents related to laboratory, laboratory accreditation, and sampling on Topical Index for Laws and Guidance from website- http://ti.afdo.org/	Yes	Annual	# of new/updated documents related to laboratory, laboratory accreditation, and sampling in Topical Index.
16	4.5 Community building and networking	Grant	Awareness of Topical Index for Laws and Guidance	AFDO	Count of number of views of documents related to laboratory, laboratory accreditation and sampling on Topical Index for Laws and Guidance.	Yes	Annual	Maintain or increase # of views of documents in the Topical Index for Laws and Guidance.

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
17	4.6 Standardized training and competency for governmental food and feed testing personnel	Grant	Active work by the Associations to finalize the IFPTI competency-based curriculum framework for Governmental Food and Feed Testing Laboratory Personnel	AFDO	Status of competency-based curriculum framework.	Yes	Annual	Progress within agreed upon deliverables of subcontract with IFPTI; Ultimately, completed competency-based curriculum for Governmental Food and Feed Testing Personnel
18	4.6 Standardized training and competency for governmental food and feed testing personnel	Grant	Providing awareness training of the Governmental Food and Feed Laboratory Curriculum	AFDO	Listing of seminars, dates, and venues of the Governmental Food and Feed Laboratory Curriculum Framework	Yes	With reports to FDA	Laboratory managers will be aware of the Governmental Food and Feed Laboratory Curriculum Framework Training
19	4.6- Standardized Training and competency for governmental food and feed testing personnel	Impact	Adoption of the Governmental Food and Feed Laboratory Curriculum to create new training	AFDO survey— Future Data Collection	Survey assessing use of Laboratory Curriculum and subsequent changes in practice (would be nice to have baseline practices, but can still assess changes/improvements in practice via self-reporting)	No	Pending completion	1. Creation of new training based on Governmental Food and Feed Laboratory Curriculum Framework; and 2. State food and feed testing

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
								personnel are creating learning plans and basing staff training needs on Governmental Food and Feed Laboratory Curriculum.
Section #5								
20	5 (5.1, 5.2, 5.3, 5.4, 5.5)- Providing forums and improving communication and collaboration	Grant	Active work by the Associations to provide forums , committee meetings and member travel, etc.,for improved communication and collaboration	APHL AAFCO AFDO	Counts from each organization	Yes	With required reports to FDA	Total # of events/committees and meetings/other events attended
21	5 (5.1, 5.2, 5.3, 5.4, 5.5)- Providing forums and improving communication and collaboration	Impact	Value of forums, committee meetings and member travel, etc., for improved communication and collaboration	APHL AAFCO AFDO survey and success stories	Anecdotal stories and/or blog posts, etc., following scientific meetings and conferences; survey to provide answer to question “Do you think that your communication with other laboratories/regulatory partners is improved since the CAP”?	No		Communication and collaboration has improved since the CAP
Section #6								

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
22	6.2- Educational opportunities	Grant	Active work by the Associations to provide trainings to laboratories seeking/ maintaining accreditation	APHL AAFCO AFDO	Count from each organization	Yes	With required reports to FDA	Increase in #trainings available
23	6.2- Educational opportunities	Grant	Awareness of pre-recorded webinars	APHL	Count # of registrations for webinars from website for individual webinars http://www.aphl.org/aphlprograms/food/laboratory-accrediation/Pages/Training-Resources.aspx	Yes	With required reports to FDA	Increase in # of registrations for webinars
24	6.2- Educational opportunities	Impact	Evidence of applied learning (e.g., webinars/ seminars)	APHL training evaluations	Follow-up survey to send to webinar registrants	No	Annual	Participants used/ applied webinar knowledge
Section #7								
25	8.2- AAFCO Quality Assurance Quality Control Guidelines	Grant	Completion of Revised AAFCO Quality Assurance Quality Control Guidelines	AAFCO	Status of the AAFCO Quality Assurance Quality Control Guidelines (completed)	Yes	One time in Y02 for completion of the AAFCO Quality Assurance Quality Control Guidelines	A revised version of AAFCO's Quality Assurance Quality Control Guidelines completed.

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
26	8.2- AAFCO Quality Assurance Quality Control Guidelines	Grant	Awareness of Revised AAFCO Quality Assurance Quality Control Guidelines	AAFCO	Provision of sales #s of publication; # of sales of the publication, list of marketing activities	Yes		QA guidelines will be available and marketed through Associations website, emails and other such venues.
27	8.2- AAFCO Quality Assurance Quality Control Guidelines	Impact	Implementation and Usage of Revised AAFCO Quality Assurance Quality Control Guidelines	survey	Survey assessing use of revised guidelines and subsequent changes in practice (would be nice to have baseline practices, but can still assess changes/improvements in practice via self-reporting)	No	One time (Y04 or Y05)	Change in QA/QC practices as a result of revised guidelines
28	8.1- Proficiency testing program for laboratories testing animal feed	Grant	Active work by the Associations to achieve ISO 17043 Accreditation of PT program for animal feed	AAFCO	Status of accreditation to ISO 17043 of the PT program for animal feed.	Yes	Annual	3rd party accreditation to ISO 17043 received.
29	8.1- Proficiency testing program for laboratories testing animal feed	Grant	Active work by the Associations to expand the PT programs for Feed Laboratories	AAFCO	Status of roll out of new programs	Yes	Annual	New analyte(s) added annually.
30	8.1- Proficiency testing program for laboratories testing animal feed	Impact		AAFCO		No		PT Program is self-supporting

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
31	8.1- Proficiency testing program for laboratories testing animal feed	Grant	Active work by the Associations to ensure use of PT programs by Feed Laboratories	AAFCO	Count from PT provider	Yes	Annual	Maintain/increase in # of laboratories enrolling in and completing PT.
Overarching ISO measures								
32	FDA ISO Cooperative Agreement- Accreditation	Impact	Success of the FDA ISO Cooperative Agreement funding to help laboratories achieve or expand their scope of their accreditation	FDA/survey by Associations	Specific stories through survey of laboratories- would obtain text/stories	No		Specific successes outlining how the FDA ISO CoAg has helped with seeking, maintaining, expanding scope of accreditation
33	FDA ISO Cooperative Agreement- Data acceptance (FDA)	Impact	Successful use of state laboratory data	FDA/survey by Associations	FDA to provide (Districts or OP?) or through survey.	No		Increase in <ul style="list-style-type: none"> • # of labs submitting data packets • # of data packets being submitted • % of data packets being accepted for regulatory action by FDA

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
34	FDA ISO Cooperative Agreement-Data acceptance (Intra/interstate)	Impact	Successful state-specific regulatory action	AFDO research	Survey to AFDO's members for specific stories of data used for state-specific regulatory action	No		Use of state-specific laboratory data for interstate/intrastate for regulatory action
35	FDA ISO Cooperative Agreement-Data acceptance	Impact	Successful use of state data for import alerts issued	FDA/survey by Associations	Counts	No		Increase in # of import alerts issued
36	FDA ISO Cooperative Agreement-Accreditation	Impact	Success of the FDA Cooperative Agreement funding to help laboratories achieve or expand the scope of their accreditation?	FDA/survey by Associations	Counts	No		Increase in # of laboratories that achieve or expand the scope of their ISO accreditation.
37	Overall aim of working towards accreditation	Impact	Success of the FDA ISO Cooperative Agreement funding to help laboratories achieve or expand the scope of their accreditation	FDA/survey by Associations	Counts	No	Annual	Increase in the # of laboratories with a quality manual.

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
38	Overall aim of working towards accreditation	Impact	Success of the FDA ISO Cooperative Agreement funding to help laboratories achieve or expand the scope of their accreditation	FDA/suvey by Associations	Counts	No	Annual	Increase in # of laboratories with a full-time Quality Mangaer
39	Overall aim of working towards accreditation	Impact	Success of the FDA ISO Cooperative Agreement funding to help laboratories achieve or expand the scope of their accreditation	FDA/suvey by Associations	Counts	No	Annual	Increase in # of laboratories who have chosen an Accrediting Body
40	Overall aim of working towards accreditation	Impact	Success of the FDA ISO Cooperative Agreement funding to help laboratories achieve or expand the scope of their accreditation internal audits	FDA /survey by Associations	Counts	No	Annual	Increase in # of laboratories who have conducted an internal audit.

	AIM/activity being measured	Grant or Impact?	What is being measured?	Who	How will it be measured?	Already doable?	Reporting Frequency	Measure of Success
41	Aim #1: Support programs	Impact	Value of Associations Cooperative Agreement on unfunded laboratories	survey by Associations	APHL as part of Yvonne Salfinger's contract deliverables	No	Annual	Increase in # of unfunded laboratories that achieved accreditation
42	Aim #1: Support programs	Impact	Value of the resources provided by the Associations to help laboratories achieve/enhance accreditation	Survey by Associations	Survey value of different components (e.g., website, documents, meetings, webinars, SMEs)	No	Annual	Specific success stories on how the accreditation resources offered by Associations helped laboratories achieve/enhance accreditation